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IN THE

Supreme Court of the United States

OCTOBER TERM, 1991

CHEMICAL SPECIALTIES MANUFACTURERS ASSOCIATION, INC.,
Petitioner,

v.

CLIFFORD L. ALLENBY; JOHN K. VAN DE KAMP, ESQ.,
Respondents.

Petition for a Writ of Certiorari to the United States Court of Appeals for the Ninth Circuit

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PETITION FOR A WRIT OF CERTIORARI

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QUESTIONS PRESENTED

Are point-of-sale warning requirements imposed by a California statute ("Proposition 65") upon manufacturers of consumer pesticides preempted by the Federal Insecticide, Fungicide, and Rodenticide Act, 7 U.S.C. §§ 136-136y (1988 & Supp. II 1990), which defines pesticide labeling broadly, vests the United States Environmental Protection Agency ("EPA") with comprehensive and exclusive authority to determine through regulation of labeling what warnings manufacturers should provide, and expressly prohibits any state requirements for labeling in addition to or different from those imposed by EPA?

Are point-of-sale warning requirements imposed by California Proposition 65 upon manufacturers of consumer products containing hazardous substances preempted by the Federal Hazardous Substances Act, 15 U.S.C. §§ 1261-1277 (1988 & Supp. II 1990), which defines labeling broadly, vests the federal Consumer Product Safety Commission ("CPSC") with comprehensive and exclusive authority to determine through regulation of cautionary labeling for consumer products what warnings manufacturers should provide, and expressly prohibits a state from establishing different cautionary labeling requirements for the same risks?

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OPINIONS BELOW

The opinion of the United States Court of Appeals for the Ninth Circuit is reported at 958 F.2d 941 (9th Cir. 1992), and is reproduced herein as Appendix ("App.") A at 1a. The decision of the United States District Court for the Northern District of California is reported at 744 F. Supp. 934 (N.D. Cal. 1990), and is reproduced herein as App. B at 20a.

JURISDICTION

The judgment of the United States Court of Appeals for the Ninth Circuit was entered on March 11, 1992. *Chemical Specialties Manufacturers Ass'n v. Allenby*, 958 F.2d 941 (9th Cir. 1992). This Court has jurisdiction under 28 U.S.C. § 1254(1) (1988).

CONSTITUTIONAL, STATUTORY, AND REGULATORY PROVISIONS INVOLVED

This case arises under Article VI, Clause 2, of the United States Constitution (the "Supremacy Clause"), which provides:

> This Constitution, and the Laws of the United States which shall be made in Pursuance thereof . . . shall be the supreme Law of the Land; and the Judges in every State shall be bound thereby, any Thing in the Constitution or Laws of any State to the Contrary notwithstanding.

U.S. Const. art. VI, cl. 2. The two federal statutes involved are the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA"), 7 U.S.C. §§ 136-136y (1988 & Supp. II 1990), and the Federal Hazardous Substances Act ("FHSA"), 15 U.S.C. §§ 1261-1277 (1988 & Supp. II 1990). The California state statute and regulations in question are the California Safe Drinking Water and Toxic Enforcement Act of 1986 ("Proposition 65"), Cal. Health & Safety Code §§ 25249.5-.13 (West Supp. 1992), and the regulations promulgated thereunder, Cal. Code Regs. tit. 22, §§ 12000-14000 (1991). The relevant portions of these statutes and regulations are set out verbatim in Petitioner's Appendix. App. C at 27a (FIFRA), 28a (FHSA), 38a (Proposition 65), and 31a (Cal. Code Regs. tit. 22, § 12601).

STATEMENT OF THE CASE

This case raises two parallel federal preemption issues: Whether California Proposition 65 point-of-sale warning requirements imposed upon manufacturers of consumer pesticides are preempted by FIFRA, and whether the same Proposition 65 warning requirements imposed upon manufacturers of other consumer products containing hazardous substances are preempted by FHSA. Each of these federal statutes vests a federal agency (the United States Environmental Protection Agency and the Consumer Product Safety Commission, respectively) with

comprehensive authority to regulate manufacturers' cautionary labeling, and each contains a provision which expressly preempts the States from establishing their own cautionary labeling requirements.

Petitioner Chemical Specialties Manufacturers Association, Inc. ("CSMA")[1] is a national trade association consisting of over four hundred companies that manufacture, formulate, distribute and sell throughout the United States, consumer products which are regulated under either FIFRA or FHSA. Concerned that Proposition 65 point-of-sale warning requirements undermine the integrity and uniformity of federally regulated cautionary labeling, and thereby jeopardize the health and safety of consumers whom the federal programs are intended to protect, Petitioner filed a Complaint in federal district court on March 2, 1989 seeking a declaratory judgment that Proposition 65 point-of-sale warning requirements for consumer products containing either pesticides or other hazardous substances are preempted by federal law.[2]

Proposition 65 is a first-of-its-kind public Initiative Measure that was conceived and promoted by environmentalist groups and approved by California voters in November 1986. *See* Cal. Health & Safety Code §§ 25249.5-.13, ch. 6.6. It establishes the following warning requirement:

> No person in the course of doing business shall knowingly and intentionally expose any individual to a chemical known to the state to cause cancer or reproductive toxicity without first giving clear and reasonable warning . . . .

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[1] CSMA has no corporate parent, and no subsidiaries which are not wholly-owned.

[2] The Complaint was originally filed in the Southern District of California, but subsequently transferred to the Eastern District of California, and then to the Northern District of California. *See Chemical Specialties Manufacturers Ass' v. Allenby*, 744 F. Supp. 934, 935 (N.D. Cal. 1990).

Cal. Health & Safety Code § 25249.6. Implementing regulations provide that manufacturers of consumer products containing "a chemical known to the state to cause cancer or reproductive toxicity in an amount which requires a warning *shall provide a warning* to any person to whom the product is sold or transferred unless the product is packaged or labeled with a clear and reasonable warning." Cal. Code Regs. tit. 22, § 12601(b)(5) (emphasis added). The required warning is intended to flow with the product through the chain of distribution from the manufacturer to the purchaser at the point of sale. *See* Cal. Health & Safety Code § 25249.11(f) (requiring that implementing regulations "shall to the extent practicable *place the obligation to provide any warning materials such as labels on the producer or packager* rather than on the retail seller") (emphasis added); *see also* Cal. Code Regs. tit. 22, § 12601(b)(2); Final Statement of Reasons (accompanying Cal. Code Regs. tit. 22, § 12601) (Oct. 6, 1988) (explaining that manufacturers must provide warning materials to accompany the product so that the retailer can transmit them to the consumer).

The Proposition 65 regulations also specify the warning language to be provided:

> The warning message must include the following language:
>
> (A) For consumer products that contain a chemical known to the state to cause cancer:
>
> "WARNING: This product contains a chemical known to the State of California to cause cancer."
>
> (B) For consumer products that contain a chemical known to the state to cause reproductive toxicity:
>
> "WARNING: This product contains a chemical known to the State of California to cause birth defects or other reproductive harm."

Cal. Code Regs. tit. 22, § 12601(b)(4).

The regulations authorize three "safe harbor" methods for transmitting the required Proposition 65 warnings:

(i) labels and labeling, (ii) shelf labeling and signs, and (iii) a system of signs with toll-free information services. *Id.* § 12601(b)(1). Each of these methods requires manufacturers to ensure that upon sale or transfer of a product, it is accompanied by product-specific written or graphic warning materials, which must be conspicuously displayed by retailers at the point of sale so as to render them "likely to be read and understood by an ordinary individual under customary conditions of purchase or use." *Id.* § 12601(b)(3); *see also id.* § 12601(b)(5); *Ingredient Communication Council, Inc. v. Van de Kamp*, No. 504601, slip op. at 14 (Cal. Super. Ct. Aug. 22, 1989) (holding that Proposition 65 requires an "in-store notification system which provides product-specific warnings"), *finalized without change* (Oct. 30, 1989), *aff'd*, 2 Cal. App. 4th 1480, 4 Cal. Rptr. 2d 216 (1992).

FIFRA vests the United States Environmental Protection Agency ("EPA") with comprehensive and exclusive authority to regulate pesticide labeling, which FIFRA defines broadly to include all "written, printed, or graphic matter . . . accompanying the pesticide . . . at any time." 7 U.S.C. § 136(p)(2) (1988). Among other human health hazards, FIFRA addresses cancer and reproductive toxicity, the same two types of hazards covered by Proposition 65 warning requirements. *See* 40 C.F.R. § 154.7(a)(2) (1991). Section 24(b) of FIFRA expressly preempts any state requirements for labeling "in addition to or different from" those established by EPA pursuant to FIFRA. 7 U.S.C. § 136v(b) (1988).[3]

FHSA vests the federal Consumer Product Safety Commission ("CPSC") with comprehensive and exclusive authority to regulate cautionary labeling for "hazardous

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[3] FIFRA § 24(a), 7 U.S.C. § 136v(a), allows states to regulate "the sale or use of any federally registered pesticide," so long as such regulation does not interfere with EPA's exclusive regulation of labeling. *See Wisconsin Public Intervenor v. Mortier*, 111 S. Ct. 2476, 2486 (1991).

substances," defined so as to exclude pesticides regulated under FIFRA. 15 U.S.C. § 1261(f)(2) (1988). FHSA's definition of "hazardous substance" includes substances which are "toxic," which in turn includes chemicals that can cause cancer or reproductive toxicity as a result of reasonably foreseeable handling or use. 15 U.S.C. § 1261 (f)(1)(A); CPSC Advisory Op. No. 309 (Mar. 19, 1987), at 2. Therefore, FHSA applies to products which may cause cancer or birth defects, the same toxic risks addressed by Proposition 65.

Section 18(b)(1)(A) of FHSA expressly preempts any different state cautionary labeling requirements addressing the same risks covered by FHSA cautionary labeling. 15 U.S.C. § 1261 note (b)(1)(A). Under FHSA, labeling encompasses "all accompanying literature where there are directions for use, written or otherwise." *Id.* § 1261(n)(2). CPSC regulations define "accompanying literature" to include point-of-sale placards, signs, or other displays. 16 C.F.R. § 1500.3(c)(9) (1992).

The district court had jurisdiction over Petitioner's declaratory judgment action pursuant to 28 U.S.C. §§ 2201 and 1331 (1988). Petitioner and Respondents (California State Government officials) filed cross-motions for summary judgment. The district court ruled in favor of Respondents, holding that there was no federal preemption. *Chemical Specialties Manufacturers Ass'n v. Allenby*, 744 F. Supp. 934 (N.D. Cal. 1990), App. B at 20a.[4] Petitioner appealed to the United States Court of Appeals for the Ninth Circuit, which conducted a *de novo* review of the district court's decision. *Chemical Specialties Manufacturers Ass'n v. Allenby*, 958 F.2d 941 (9th Cir. 1992), App. A at 1a.

Parallel preemption arguments under FIFRA and FHSA were presented by Petitioner to the court of appeals. With respect to consumer pesticides, Petitioner

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[4] The district court incorporated by reference its anti-preemption FIFRA holding in *d-Con Co. v. Allenby*, 728 F. Supp. 605, 607 (N.D. Cal. 1989).

argued that Proposition 65 warning requirements are expressly preempted by FIFRA § 24(b), since they are state requirements for labeling in addition to and different from those required by EPA pursuant to FIFRA. Petitioner also contended that even if Proposition 65 point-of-sale warnings are not labeling, they are impliedly preempted by FIFRA because they frustrate Congress' goals for, undermine the integrity of, and interfere with the national uniformity of, EPA's cautionary labeling for each pesticide product.

The Ninth Circuit held that Proposition 65 warnings are not FIFRA labeling (improperly distinguishing this Court's holding in *Kordel v. United States*, 335 U.S. 345 (1948)). *Allenby*, App. A at 9a. Furthermore, the court of appeals explicitly declined to consider the question of frustration of congressional purpose, and rejected Petitioner's other implied preemption arguments under FIFRA. *Id.* at 13a-16a.

The Ninth Circuit also held that Proposition 65 warnings are not expressly or impliedly preempted by FHSA. *Id.* at 16a-19a. Petitioner contended that Proposition 65 point-of-sale warning signs for consumer products containing hazardous substances are labeling within the meaning of FHSA, and therefore, are barred by FHSA's express preemption provision. In this regard, Petitioner submitted, but the court of appeals failed to consider, a formal Advisory Opinion from CPSC's General Counsel interpreting FHSA's cautionary labeling provisions as encompassing Proposition 65 warnings. CPSC Advisory Op. No. 312 (Mar. 6, 1991), App. D at 39a. Petitioner also argued that even if Proposition 65 warnings are not FHSA labeling, they are preempted because they frustrate the congressional purpose of nationally uniform labeling.

REASONS FOR GRANTING THE WRIT

This case raises a nationally significant issue: Do the States have free reign to undermine the integrity of federally regulated cautionary labeling for consumer prod-

ucts containing pesticides or other hazardous substances by requiring manufacturers to give different and even conflicting warnings for the same products at the point of sale? The court of appeals circumvented this critical issue by focusing on the narrow question of whether point-of-sale warning signs for cancer and reproductive toxicity required by California Proposition 65 are "labeling" within the meanings of FIFRA and FHSA, and by erroneously concluding that they are not.

If left undisturbed, this ruling, which conflicts with the Supreme Court's long-standing, broad view of the term "labeling" in federal regulatory statutes, will clear the way for California, whose huge population accounts for a substantial percentage of consumer pesticides and household hazardous substances used in the United States, to expand Proposition 65 or enact similar laws to mandate warnings that would be different for any type of hazard (e.g., acute toxicity, flammability, corrosivity, explosivity) already covered by federally regulated FIFRA and FHSA cautionary labeling. Moreover, because other States look to California as a legislative trendsetter (Proposition 65 was the first law of its kind in the United States), there is a distinct possibility that, as a result of the Ninth Circuit's decision, numerous States each will enact its own Proposition 65-type warning scheme. The court's ruling allows each State to utilize its own risk criteria and to devise its own warning language, even if they conflict with those of other States, as well as with those of EPA or CPSC.[5] Thus, because this case will have far-reaching, nationwide consequences for the FIFRA and FHSA cautionary labeling programs for consumer products, the Supreme Court should exercise its discretionary jurisdiction to review the Ninth Circuit's defective and deficient preemption analysis.

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[5] States which are considering or have considered enacting Proposition 65-type statutes include New York, Massachusetts, West Virginia, Illinois, Ohio, Tennessee, Louisiana, Washington, Oregon, and Hawaii.

I. THE FEDERAL PREEMPTION ISSUE IN THIS CASE IS OF PARAMOUNT IMPORTANCE TO PRESERVING THE INTEGRITY OF FEDERAL CAUTIONARY LABELING FOR PESTICIDES AND OTHER HAZARDOUS SUBSTANCES

The fundamental purpose of nationally uniform, federally regulated cautionary labeling is to protect the health and safety of persons who purchase or use pesticides or other products containing hazardous substances. If the Ninth Circuit's decision is allowed to stand, California and every other State will be free to frustrate that purpose by second-guessing or ignoring federal warning determinations, which are reflected on each consumer product's federally regulated labeling, and by enacting different or conflicting point-of-sale warning requirements for the same product.

For example, if EPA finds that the weight of toxicology evidence on a particular pesticide indicates no significant human health risk of cancer or reproductive effects, EPA will not require a label warning. If that same pesticide, however, is listed under the inflexible criteria of Proposition 65 as a carcinogen and reproductive toxin, Proposition 65 point-of-sale cancer and reproductive toxicity warnings will be required. Thus, Proposition 65 warnings will conflict or be inconsistent with EPA warning determinations. As another example, a consumer product which poses a *possible* cancer risk would require a Proposition 65 point-of-sale warning using the signal word "Warning" and the phrase "Known to the State to Cause Cancer," even though that differs from the wording of the cautionary labeling required under FHSA, which incorporates a careful hierarchy of signal words depending upon the degree of risk presented (e.g., "*Caution*" in the case of possible carcinogens, and "Warning" only in the case of *known* carcinogens). *See* 15 U.S.C. § 1261(p)(1). By universally requiring the signal word "Warning," Proposition 65 deviates from federal practice on signal

words and creates conflicts or inconsistencies with federal cautionary labeling.

Consequently, unless Proposition 65 warning requirements are preempted, manufacturers will be confronted with the perilous task of giving conflicting or inconsistent federal and state warnings about the same product. Federal cautionary labeling, which now reflects careful, product-by-product scientific determinations under FIFRA or FHSA as to the specific hazards to be addressed and the precise warning information to be given, will become a source of uncertainty and confusion, if not altogether superfluous. By undermining the integrity of the federal labeling program under FIFRA and FHSA, Proposition 65 jeopardizes Congress' primary means for protecting the health and safety of consumers. Indeed, to prevent this very result, Congress included in both FIFRA and FHSA provisions which expressly preempt any additional or different State requirements for labeling, such as those imposed upon manufacturers by Proposition 65.

Cautionary labeling is the regulatory centerpiece and principal enforcement mechanism of both FIFRA and FHSA. It is the means by which EPA or CPSC ensures that product manufacturers communicate to purchasers and users the *precise* warnings (and precautionary information) which the federal government has determined are necessary to protect the health and safety of the consumer. Indeed, the whole purpose of federally regulated labeling is to get consumers to read, understand and follow label warnings and precautionary information.[6]

In the case of FIFRA, rather than include every conceivable warning and hazard on a pesticide's label or labeling, EPA painstakingly assesses scientific data on each regulated pesticide product to ensure that the warnings provided are only those which truly are necessary,

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[6] FIFRA makes it unlawful for any person "to use any registered pesticide in a manner inconsistent with its labeling." 7 U.S.C. § 136j(a)(2)(G).

that they are worded accurately and appropriately in comparison to other warnings on the same label and on labels of similar products, and that their impact is not diluted by unnecessary, conflicting, or inconsistent warnings. FIFRA's preemption provision, section 24(b), enables EPA to accomplish this congressional objective of protecting consumers.

In *New York State Pesticide Coalition, Inc. v. Jorling*, 704 F. Supp. 26 (N.D.N.Y.), *aff'd*, 874 F.2d 115 (2d Cir. 1989), the federal district court explained FIFRA § 24(b) as follows:

> This court reads the language of 7 U.S.C. § 136v (b) which prohibits states from requiring labeling "in addition to or different from" that approved by the EPA *as having its main focus upon preserving the force of the information contained in the FIFRA label. Attention to the label's dictates would work to prevent "unreasonable adverse effects on the environment."* 7 U.S.C. § 136a(c)(5).
>
> . . . Moreover, it is likely that in defining the precise informational content of a label the EPA is concerned as much with what goes into the language of the label as what does not. *Placing every potential warning or use requirement onto the label could operate to dilute the most important instructions and thus violate the EPA's exclusive authority to label.*

704 F. Supp. at 29-30 (emphasis added). Thus, requiring a pesticide manufacturer to provide a cancer or reproductive toxicity warning which is unnecessary, or is worded in a way that implies a greater hazard than actually exists, detracts from other warnings (e.g., acute hazard to eyes or skin) which are necessary and must be followed by purchasers and users for their own protection.

This is no less true for Proposition 65 point-of-sale warnings than for conflicting or inconsistent warnings appearing on the face of a federally mandated pesticide label. Similarly, in the case of consumer products regulated by FHSA, Congress sought to ensure that caution-

ary labeling is not encumbered by unnecessary warnings, "thus inviting indifference to cautionary statements on packages of substances presenting a real hazard of substantial injury or illness." H.R. Rep. No. 1861, 86th Cong., 2d Sess. (1960), *reprinted in* 1960 U.S.C.C.A.N. 2833, 2837. Therefore, ensuring that consumer products are "free of differing labeling requirements was clearly of foremost concern to Congress in enacting the [FHSA] preemption provision." *Chemical Specialties Manufacturers Ass'n v. Lowery*, 452 F.2d 431, 438 (2d Cir. 1971).

The Ninth Circuit's opinion is an open invitation for California to adopt warning requirements for any federally regulated hazard, and for other States to enact their own versions of Proposition 65, thereby further sabotaging the exclusively federal, cautionary labeling programs established by Congress through enactment of FIFRA and FHSA. The crucial issue raised by the Ninth Circuit's anti-preemption ruling, therefore, is whether these federal programs should be permitted to fulfill their intended purpose of protecting the public, unobstructed by as many as fifty different state point-of-sale warning schemes for consumer product manufacturers. This is a question worthy of Supreme Court review because of the disastrous consequences which otherwise will follow from the Ninth Circuit's opinion.

II. THE NINTH CIRCUIT'S DECISION JEOPARDIZES FIFRA'S PESTICIDE LABELING PROGRAM BY ALLOWING STATES TO UNDERMINE FEDERAL PRODUCT-SPECIFIC WARNINGS INTENDED TO PROTECT PUBLIC HEALTH AND SAFETY

A. Congress Expressly Preempted State Requirements for Pesticide Labeling By Authorizing EPA Alone to Specify Nationally Uniform Cautionary Labeling for Each Pesticide Product

Twice before this Court has recognized that "FIFRA's historic focus [is] on labeling." *Mortier*, 111 S. Ct. at 2486 (citing *Ruckelshaus v. Monsanto Co.*, 467 U.S. 986,

991 (1984)). "FIFRA as originally adopted 'was primarily a licensing and labeling statute.'" *Mortier*, 111 S. Ct. at 2479 (quoting *Monsanto*, 467 U.S. at 991). When Congress rewrote FIFRA in 1972, it "significantly strengthened FIFRA's registration and labeling standards." 111 S. Ct. at 2479. Indeed, "the general goal of the 1972 amendments [was] to strengthen existing labeling requirements and insure that these requirements were followed in practice." *Id.* at 2486 (citations omitted). In this manner, Congress sought to "protect man and his environment," including by "extend[ing] Federal pesticide regulation to actions entirely within a single State." S. Rep. No. 838, 92d Cong., 2d Sess. (1972), *reprinted in* 1972 U.S.C.C.A.N. 3993, 3993.

1. *EPA's Broad Authority Over Pesticide Labeling*

To protect public health and the environment, Congress has vested EPA with comprehensive and exclusive authority to regulate pesticide labeling.[7] Pursuant to this authority, "EPA has regulated almost every aspect of pesticide labeling." *Papas v. Upjohn Co.*, 926 F.2d 1019, 1024 (11th Cir. 1991), *petition for cert. filed sub nom. Papas*

[7] "Labeling" means "all labels and all other written, printed, or graphic matter—(A) accompanying the pesticide . . . at any time; or (B) to which reference is made on the label or in literature accompanying the pesticide." 7 U.S.C. § 136(p)(2). EPA may register a pesticide only if it first determines that the product, when used in accordance with its labeling, will not cause "unreasonable adverse effects" to man or the environment. *Id.* §§ 136a(c)(5), 136(bb) (1988). In addition, EPA must determine that a pesticide's labeling complies with the other requirements of FIFRA, including that the product is not "misbranded." *See id.* § 136(q); 40 C.F.R. § 152.112(f) (1991) (approval of registration). A pesticide is misbranded if, *inter alia*, "the label does not contain a warning or caution statement which may be necessary and if complied with . . . is adequate to protect health and the environment." 7 U.S.C. § 136(q)(1)(G). A pesticide also is misbranded if "the labeling accompanying it does not contain directions for use which . . . are adequate to protect health and the environment." *Id.* § 136(q)(1)(F).

v. Zoecon Corp., 59 U.S.L.W. 3825 (U.S. May 29, 1991) (No. 90-1837); *see* 40 C.F.R. pt. 156 (1991).

In particular, EPA determines through regulation of labeling what warnings pesticide manufacturers should provide in connection with sale or use of their products. Pesticide labeling "must show clearly and prominently . . . [w]arning or precautionary statements as prescribed" by EPA. 40 C.F.R. § 156.10(a)(1)(vii). The warnings and precautionary statements specified by EPA encompass cancer, reproductive toxicity, and any other hazards to persons who use or may be exposed to a pesticide. *See id.* § 158.340 (1991). "Where a hazard exists to humans . . . precautionary statements are required indicating the particular hazard, the route(s) of exposure and the precautions to be taken to avoid accident, injury or damage." *Id.* § 156.10(h)(2)(i)(A). Furthermore, label directions "must be adequate to protect the public from . . . personal injury and to prevent unreasonable adverse effects." *Id.* § 156.10(i).

EPA is uniquely qualified to perform the task of regulating pesticide manufacturers' cautionary labeling. It has the national perspective, as well as the necessary scientific data, technical resources, expertise and experience, to determine which specific warnings are warranted, and which are not, for each pesticide product. By vesting EPA with comprehensive authority over labeling, Congress sought to "provide for a more finely tuned control of pesticides." S. Rep. No. 838, 92d Cong., 2d Sess. (1972), *reprinted in* 1972 U.S.C.C.A.N. at 3997. Thus, rather than limiting warnings to vague, generalized statements (such as those required by Proposition 65), EPA determines on the basis of each product's particular ingredients, toxicity and uses, what specific warnings, prohibitions, and precautionary measures are necessary to protect the health and safety of persons who purchase, use or may be exposed to the pesticide. EPA makes these product-by-product cautionary labeling determinations af-

ter reviewing numerous types of state-of-the-art scientific studies, which EPA requires pesticide manufacturers to conduct in accordance with stringent protocols. *See* 7 U.S.C. § 136a(c)(2)(A), (B); 40 C.F.R. pt. 158 (1991).

Through labeling, EPA seeks to prevent pesticide misuse. *See* 7 U.S.C. § 136j(a)(2)(G), making it unlawful to use a pesticide "in a manner inconsistent with its labeling." Misuse cannot be avoided unless label warnings are clear, read and followed. Proposition 65 point-of-sale warnings frustrate this goal by diverting attention away from, and undermining the integrity of, EPA-regulated labeling, thus diminishing its effectiveness in preventing misuse and protecting health.

2. *FIFRA's Express Prohibition Against State Labeling Requirements*

To achieve its objective of vesting EPA with absolute authority over pesticide manufacturers' precautionary labeling and warnings, Congress enacted FIFRA § 24(b), entitled "Uniformity," which expressly provides that no state shall "impose or continue in effect any requirements for labeling or packaging in addition to or different from those required under [FIFRA]." 7 U.S.C. § 136v(b). Congress intended this provision "to completely preempt State authority in regard to labeling." H.R. Rep. No. 511, 92d Cong., 1st Sess. 16 (1971); *see also* S. Rep. No. 838, 92d Cong., 2d Sess. (1972), *reprinted in* 1972 U.S.C.C.A.N. at 4021. Because "FIFRA place[s] the 'labeling' of pesticides within the singular province of the EPA," a state cannot second-guess or in any way supplement the cautionary labeling specified by EPA. *Jorling*, 874 F.2d at 117. As a result, "[u]nder FIFRA, the federal government—through the EPA—has the sole and exclusive right to regulate pesticide label[ing]." *Papas*, 926 F.2d at 1024.

While FIFRA does not prevent a state from restricting or even banning the use of an EPA-registered pesticide, section 24(b) makes it clear that labeling "fall[s] within an area that FIFRA's 'program' pre-empts." *Mortier*, 111 S. Ct. at 2487. The court of appeals recognized this same limitation on state authority over pesticides. *Allenby*, App. A at 9a ("We agree that additional labeling requirements would be unconstitutional under FIFRA."). Other than regulating labels, "states are left free to impose whatever restrictions they may wish." *Id.* at 7a; *see also Arkansas-Platte & Gulf Partnership v. Van Waters & Rogers, Inc.*, 959 F.2d 158, 160 (10th Cir. 1992) ("A plain reading of the statute indicates an intent to maintain the traditional police powers of the states in the general grant of authority to 'regulate the sale or use' of pesticides, § 136v(a), and a more specific intent to occupy the field in labeling and packaging, § 136v(b)."); *Papas*, 926 F.2d at 1024 (alteration in original) (citations omitted) ("While states can regulate the sale or use of federally registered pesticides, no state can 'impose or continue in effect any requirements for labeling or packaging [of pesticides] in addition to or different from' those required by FIFRA."); *Jorling*, 874 F.2d at 118 (citation omitted) ("The states have joint control with the federal government in regulating use of pesticides, for the safety of its citizens and their environment with the exception of the EPA's exclusive supervision of labeling.").

Congress' objective in preempting state labeling requirements is to protect public health and safety, and also the environment, by imposing upon manufacturers the duty to distribute their products only with uniform cautionary labeling containing warnings specified solely by EPA. The court of appeals acknowledged that "Congress included the preemption provision in FIFRA to promote uniformity." *Allenby*, App. A at 7a; *see also Arkansas-Platte & Gulf Partnership*, 959 F.2d at 162 ("[T]he full purpose of [§ 24(b)] . . . is to ensure uniform labeling standards."); *Papas*, 926 F.2d at 1025 n.6

("This desire for uniformity is particularly evident in the regulation of pesticide warnings."). Nationally uniform cautionary labeling for each pesticide product fulfills FIFRA's fundamental purpose of protecting public health and the environment by promoting user comprehension and avoiding confusion over conflicting or inconsistent warnings. Thus, "FIFRA's prohibition of state labeling . . . has as 'its main focus . . . preserving the force of the information contained in the FIFRA label.'" *Jorling*, 874 F.2d at 119.

If each state had the authority to devise its own cautionary labeling (or point-of-sale warnings based on its own risk criteria) for the same pesticide product, Congress' goals would be frustrated. Not only would national uniformity be destroyed, but also the integrity of EPA's warning determinations reflected on each product's labeling would be seriously impaired by additional, different, inconsistent or conflicting state warning requirements. For example, if a state point-of-sale warning sign provided a cancer warning but the FIFRA label did not, the integrity of the FIFRA label would suffer because of its seeming inadequacy. Similarly, if a state warning sign used the phrase "Extreme Hazard to Eyes" in referring to a slight eye irritation hazard which the FIFRA label addressed by the phrase "Caution: Avoid Contact With Eyes," the credibility of the FIFRA precautionary statement would be impaired, and more serious warnings on the label might be ignored. Thus, without preemption of state labeling requirements, the very purpose of FIFRA and its labeling program—to protect public health and safety—would be jeopardized.

B. The Court Deviated From Well-Established Principles of Preemption By Failing to Consider Whether Proposition 65 Frustrates Congress' Goals for Cautionary Labeling Under FIFRA

Regardless of whether Proposition 65 warning requirements fall literally within FIFRA's definition of labeling, they also are preempted if they "stand[] as an obstacle

to the accomplishment and execution of the full purposes and objectives of Congress." *Mortier*, 111 S. Ct. at 2482 (quoting *Hines v. Davidowitz*, 312 U.S. 52, 67 (1941)). "A state law—even if it has the same ultimate goal as a federal law—may stand as an obstacle to the full implementation of a federal law and therefore be preempted 'if it interferes with the methods by which the federal statute was designed to reach this goal.'" *Papas*, 926 F.2d at 1021-22 (quoting *International Paper Co. v. Ouellette*, 479 U.S. 481, 494 (1987)); *see also Arkansas-Platte & Gulf Partnership*, 959 F.2d at 161.

The court of appeals flagrantly deviated from this long established principle of implied preemption by failing to consider whether Proposition 65 warning requirements frustrate the congressional goals underlying FIFRA's labeling program. Rather than taking Congress' objectives into account, the court erroneously determined that it "need not consider whether Proposition 65 frustrates congressional purpose." *Allenby*, App. A at 16a.

According to the court, such an analysis is unnecessary because of "the possibility of complying with both Proposition 65 and FIFRA." *Id.* This non-sequitur confuses two *separate* ways in which state and federal law may "actually conflict" for purposes of implied preemption:

> [P]re-emption may occur to the extent that state and federal law actually conflict. Such a conflict arises when "compliance with both federal and state regulations is a physical impossibility," *Florida Lime & Avocado Growers, Inc. v. Paul*, 373 U.S. 132, 142-143, 83 S.Ct. 1210, 1217, 10 L.Ed.2d 248 (1963), *or* when a state law "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress," *Hines v. Davidowitz*, 312 U.S. 52, 61 S.Ct. 399, 85 L.Ed. 581 (1941).

Mortier, 111 S. Ct. at 2482 (emphasis added). Thus, physical impossibility of dual compliance is one way that

a state law may conflict with a federal law, and frustration of congressional purpose is another.[8]

The court of appeals' explicit refusal to consider the question of whether Proposition 65 warning requirements frustrate FIFRA's purpose—an issue which Petitioner briefed extensively—renders the court's FIFRA preemption analysis flawed and incomplete, and given the potential ramifications of this error, is reason enough for this Court to grant a writ of certiorari.[9]

C. The Court Failed to Recognize That the Undisputed Conflict Between Proposition 65 Warning Requirements and EPA-Mandated Pesticide Labeling Diminishes the Integrity of the Labeling and Compels Preemption

The district court record contains several examples of conflicting or inconsistent Proposition 65 and EPA warnings for specific pesticides. These conflicts arise because Proposition 65 mandates use of inflexible risk criteria, which trigger point-of-sale warning requirements. Those criteria differ substantially from EPA's "weight-of-the-evidence" approach to risk assessment. California and EPA separately utilize their different criteria to assess the risks associated with use of a particular pesticide,

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[8] Elsewhere in its opinion the court acknowledges that "state law may be preempted if it . . . stands as an obstacle to the achievement of federal objectives." *Allenby*, App. A at 4a (citing *Silkwood v. Kerr-McGee Corp.*, 464 U.S. 238, 248 (1984)).

[9] Although it may be physically possible for a pesticide manufacturer to comply with both FIFRA and Proposition 65, the court also failed to consider the fact that the manufacturer may have to obtain EPA's approval of point-of-sale signs in order to avoid committing an unlawful act under FIFRA since such signs fall within the definition of pesticide labeling. *See* 7 U.S.C. § 136j(a)(2)(A) (making it unlawful to use any labeling not approved by EPA under FIFRA); 49 Fed. Reg. 37,960, 37,972 (1984) (proposed definition of FIFRA labeling encompassing "any . . . printed or graphic matter . . . which accompanies the product at any time in distribution or sale").

and then independently require significantly different warning language to address the same risks. In some instances, the inflexible criteria of Proposition 65 require a warning even though EPA's more "finely tuned" risk assessment does not.

Petitioner submitted to the district court affidavits from former EPA pesiticide administrators explaining how the enforceability and integrity of FIFRA labeling for consumer pesticide products is impaired by Proposition 65. In particular, consumers will regard the FIFRA labeling for a pesticide which also has Proposition 65 warnings to be incomplete, confusing, or unreliable if the FIFRA labeling for the same product does not contain a cancer or reproductive toxicity warning, or if it contains differently worded warnings than those mandated by Proposition 65. Consumers will lose confidence in such FIFRA labeling despite the fact that EPA has carefully assessed the risks of the pesticide and determined what warnings, if any, are warranted.

This problem will be compounded if, as a result of the Ninth Circuit's decision, California ever were to expand Proposition 65 to require point-of-sale warnings for other types of hazards already regulated by FIFRA labeling. The same would be true if other States enact their own versions of Proposition 65 utilizing their own risk criteria and warnings, even if they conflict with EPA's and other States' risk criteria and warning requirements. The overall result will be to defeat the very purpose of FIFRA's labeling program. This is because consumers will ignore or give short shrift to FIFRA label warnings (including warnings and precautions not covered by Proposition 65 or other States' similar schemes) since the federal labeling program depends completely on reading and following the label.

The court's implied preemption analysis fails to take into account the deleterious effects that Proposition 65 warning requirements have on EPA's FIFRA labeling

program. Nor does the court's opinion recognize that, by pressuring pesticide manufacturers to seek label changes to conform with state-imposed warning requirements, Proposition 65 will have a potentially devastating effect on EPA's maintenance of nationally uniform label warnings. *Allenby*, App. A at 16a. "'[I]n implied preemption analysis it is possible to infer preemptive intent solely from effects': even if statutory language or legislative history is unclear, federal law preempts state law if 'the ordinary application of the two laws creates a conflict.'" *Papas*, 926 F.2d at 1019 (quoting *Taylor v. General Motors Corp.*, 875 F.2d 816, 826 (11th Cir. 1989), *cert. denied*, 110 S. Ct. 1781 (1990)). Therefore, regardless of whether Proposition 65 warnings are "labeling" within the meaning of FIFRA, they are preempted because they will interfere with the credibility and uniformity of FIFRA cautionary labeling, which Congress intended to protect public health and safety.

III. THE NINTH CIRCUIT'S ERRONEOUS INTERPRETATION OF PESTICIDE LABELING CONFLICTS WITH PREVIOUS OPINIONS OF THIS COURT AND THE SECOND CIRCUIT

Proposition 65 warning requirements not only are impliedly preempted by FIFRA since they interfere with Congress' goal of nationally uniform cautionary labeling regulated solely by EPA, but also are expressly preempted by FIFRA § 24(b) since they are "requirements for labeling . . . in addition to or different from those required under [FIFRA]." 7 U.S.C. § 136v(b). The court of appeals agreed that "additional labeling requirements would be unconstitutional under FIFRA," but disagreed "that the warning requirements of Proposition 65 constitute additional labeling." *Allenby*, App. A at 9a. By holding that Proposition 65 warnings are not labeling within the meaning of FIFRA, the Ninth Circuit's opinion directly conflicts with the Supreme Court's opinion in *Kordel*, 335 U.S. 345, and the Second Circuit's opinion in *Jorling*, 874 F.2d 115.

In *Kordel*, the Supreme Court interpreted the Federal Food, Drug, and Cosmetic Act's definition of labeling, which is virtually identical to FIFRA's.[10] The Court held that written, printed, or graphic information which is used in connection with the sale of a product, and which "supplements or explains" the product or its label, should be construed as "accompanying" the product, and hence as labeling. 335 U.S. at 350. Further, "[n]o physical attachment one to the other is necessary. *It is the textual relationship that is significant.*" *Id.* (emphasis added); *see also United States v. 47 Bottles, More or Less*, 320 F.2d 564, 568 (3d Cir.) (explanatory leaflets sent out two months prior to shipment of product were labeling), *cert. denied sub nom.* 375 U.S. 953 (1963).

The opinion below conflicts with this Court's holding in *Kordel* regarding the meaning of "accompanying." Proposition 65 point-of-sale warnings are "written, printed, or graphic matter . . . accompanying" a pesticide, and therefore are pesticide labeling, because such warnings supplement or explain, and have a textual relationship with, the pesticide and its EPA-regulated label. 7 U.S.C. § 136(p)(2) (defining pesticide labeling as "all labels and all other written, printed, or graphic matter . . . accompanying the pesticide . . . at any time"); Cal. Code Regs. tit. 22, § 12601(d)(1)(A) (defining a Proposition 65 point-of-sale warning sign as "a presentation of written, printed, or graphic matter"). The court of appeals failed to recognize this relationship, as indicated by its inapt attempt to compare Proposition 65 warnings to "price stickers affixed to shelves" and "sheets indicat-

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[10] The statutory provision involved in *Kordel* defined labeling as "all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article." *Kordel*, 335 U.S. at 348 (footnote omitted) (quoting section 201(m) of the Federal Food, Drug, and Cosmetic Act); *see FIFRA* § 2(p)(2), 7 U.S.C. § 136(p)(2).

ing that a product is on sale." *Allenby*, App. A at 10a.[11] The court also attempted to distinguish *Kordel* on its facts by noting that the labeling in that case was aimed at the ultimate user of the product. Typically, however, consumers targeted by Proposition 65 are the ultimate users of the household products which they purchase. Thus, there is no basis for distinguishing *Kordel*, whose broad view of product labeling has been the law for decades.

The court's opinion conflicts with the Second Circuit's opinion in *Jorling* as well. Consistent with the Supreme Court's opinion in *Kordel*, the Second Circuit explained that FIFRA "'[l]abeling' is better understood by its relationship, rather than its proximity, to the product." *Jorling*, 874 F.2d at 119. The court's rationale below, that Proposition 65 warnings are not labeling because "[p]oint-of-sale signs are not attached to the immediate container of a product and will not accompany the product during the period of use," is contrary to *Kordel* and *Jorling* because it focuses on the physical proximity of the Proposition 65 warning to the product, rather than on the warning's relationship to the product. *Allenby*, App. A at 11a.

The court of appeals also misunderstood the nature of the state law at issue in *Jorling*. In contrast to Proposition 65 warning requirements, which are imposed upon pesticide manufacturers, *Jorling* involved state regulations requiring commercial pesticide *applicators* (i.e., users) to provide certain public notifications about their commercial pesticide application activities. There is no suggestion in *Jorling* that pesticide manufacturers, which are required to distribute their products with EPA-mandated cautionary labeling, can or should be subject to additional labeling requirements imposed by state law in violation of FIFRA § 24(b).

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[11] In so doing, the court unjustifiably and inappropriately diminished the importance of cautionary labeling, which is at the heart of FIFRA's pesticide program.

IV. THE NINTH CIRCUIT'S DECISION ALSO UNDERMINES FEDERAL WARNING DETERMINATIONS FOR CONSUMER PRODUCTS CONTAINING HAZARDOUS SUBSTANCES

The court of appeals found that "[t]he preemption issues arising under FHSA are identical to those arising under FIFRA." *Allenby*, App. A at 8a. Further, the court agreed that "FHSA [§ 18(b)] expressly preempts all state mandated precautionary labeling that is not identical to that required by the Act." *Id.* at 16a; *see* 15 U.S.C. § 1261 note (b)(1). The court again focused, however, on whether Proposition 65 warnings are labeling, and as in the case of FIFRA, reached the wrong conclusion. Furthermore, the court failed to recognize that even if Proposition 65 warning requirements are not strictly labeling within the meaning of FHSA, they nevertheless are preempted because they obstruct Congress' goals.

A. Congress Expressly Preempted State Requirements for Cautionary Labeling of Hazardous Substances By Establishing Through FHSA Nationally Uniform Cautionary Labeling for Each Consumer Product

FHSA § 18(b)(1)(A) provides that "no State . . . may establish or continue in effect a cautionary labeling requirement applicable to [a hazardous] substance . . . and designed to protect against the same risk of illness or injury unless such cautionary labeling requirement is identical to the labeling requirement under [FHSA] section 2(p) or 3(b)." 15 U.S.C. § 1261 note (b)(1).[12] "Under the FHSA . . . 'all accompanying literature where

[12] If a state wishes to impose different cautionary labeling requirements, it must petition CPSC for an exemption from the "identicality" requirement. 15 U.S.C. § 1261 note (b)(3). In determining whether to grant such an exemption, CPSC must consider "the need for a national, uniform requirement under [FHSA] for such substance." *Id.* § 1261 note (b)(3)(A). Not surprisingly, California has sought no such exemption.

there are directions for use, written or otherwise' is defined as cautionary labeling," and is subject to this express preemption provision. *Allenby*, App. A at 16a-17a (quoting FHSA § 2(n), 15 U.S.C. § 1261(n)(2)). Moreover, as the court of appeals explained, CPSC regulations define "accompanying literature" as "[a]ny *placard*, pamphlet, booklet, book, *sign*, or other written, printed, or graphic matter or visual device that provides directions for use, written or otherwise, and that is used in connection with the *display*, *sale*, demonstration, or *merchandising* of a hazardous substance intended for . . . use in the household or by children." *Allenby*, App. A at 17a (alterations in original) (emphasis added) (citing 16 C.F.R. § 1500.3(c)(9)).

Congress expressly preempted state requirements for cautionary labeling of consumer products containing hazardous substances subject to FHSA in order to protect public health and safety through a system of nationally uniform cautionary labeling regulated solely by CPSC. In enacting FHSA in 1960, Congress declared that FHSA would "provide nationally uniform requirements for adequate cautionary labeling of packages of hazardous substances." H.R. Rep. No. 1861, 86th Cong., 2d Sess. (1960), *reprinted in* 1960 U.S.C.C.A.N. at 2833. Congress explained that

> *nationwide uniformity* in the labeling of potentially hazardous chemicals *would be advantageous to everybody*. Such a labeling program would facilitate the education of the public in the cautionary use of these products.
>
> . . . In the absence of a Federal law, there is a possibility that diverse labeling regulations will be adopted by the States, leading to a *multiplicity of requirements and creating unnecessary confusion in labeling, to the detriment of the public.*

Id. at 2835 (emphasis added).

To achieve nationwide uniformity in cautionary labeling, Congress amended FHSA in 1966 by adding a pre-

emption provision. Congress found that "[i]t is *impractical, unnecessary, and undesirable for each such product to be labeled specially* for those States and cities which have developed *their own standards for requiring warnings and their own special forms of warnings* over the years during which there was no Federal law." H.R. Rep. No. 2166, 89th Cong., 2d Sess. (1966), *reprinted in* 1966 U.S.C.C.A.N. at 4097 (emphasis added); *see also Lowery*, 452 F.2d at 437. The current version of FHSA's preemption provision, as was the original, is "limited" only in the sense that the States are not precluded from imposing warning requirements "if the hazard involved is of a kind not dealt with by the Federal act." H.R. Rep. No. 2166, 89th Cong., 2d Sess. (1966), *reprinted in* 1966 U.S.C.C.A.N. at 4097. Cancer and reproductive toxicity, the hazards covered by Proposition 65, are encompassed by FHSA cautionary labeling requirements, and therefore, the preemption provision applies to Proposition 65 warnings. *See* FHSA §§ 2(p) and 3(b), 15 U.S.C. §§ 1261(p) and 1262(b).

B. The Court Erroneously Concluded That Proposition 65 Point-of-Sale Warnings Do Not Frustrate Congress' Goals for Cautionary Labeling Under FHSA

The court of appeals misconstrued the purposes of FHSA's preemption provision in concluding that "no congressional purpose [of FHSA] [is] frustrated by Proposition 65." *Allenby*, App. A at 18a. There is ample legislative history underscoring Congress' intent to protect public health and safety by avoiding consumer confusion over a multiplicity of conflicting or inconsistent product warnings. "It is the states' and cities' 'own special forms of warnings' which the Federal Hazardous Substances Act 'limited preemption amendment' is directed against." *Lowery*, 452 F.2d at 443 (Oakes, J., dissenting) (quoting H.R. Rep. No. 2166, 89th Cong., 2d Sess. (1966)).

Nevertheless, the court below viewed preemption merely as a compromise to "ease the burden of compliance for chemical product manufacturers by relieving them from the burden of complying with fifty-one separate regulatory schemes." *Allenby*, App. A at 19a. While the marketing burden certainly is one goal of the FHSA preemption provision, it is not the only or even primary objective, especially when viewed in the context of the entire Act; Congress intended foremost to ensure "better labeling of poisonous and hazardous materials that are brought into the home." H.R. Rep. No. 1861, 86th Cong., 2d Sess. (1960), *reprinted in* 1960 U.S.C.C.A.N. at 2833-34.

As in the case of FIFRA, the court failed to consider that Proposition 65 warnings, which conflict or are inconsistent with federally required cautionary labeling, undermine the integrity of the warnings on the FHSA labeling. They defeat the fundamental purpose of FHSA, which is "to require precautionary labeling which is meaningful and will be observed by the user." S. Rep. No. 1158, 86th Cong., 2d Sess. 11 (1960). By diverting consumer attention away from the warning on the product label, Proposition 65 unravels the congressionally woven fabric of FHSA.

V. THE NINTH CIRCUIT FAILED EVEN TO CONSIDER CPSC'S INTERPRETATION OF FHSA, MUCH LESS GIVE IT THE DEFERENCE WHICH THIS COURT REPEATEDLY HAS HELD SHOULD BE AFFORDED TO AN AGENCY'S INTERPRETATION OF ITS OWN STATUTE

The court of appeals based its conclusion that Proposition 65 point-of-sale warnings are not FHSA labeling primarily on its erroneous "common sense" finding that they are not "directions for use." *Allenby*, App. A at 18a. The court's opinion, however, never mentions the formal Advisory Opinion rendered by CPSC's General Counsel on this very question of statutory construction. CPSC Ad-

visory Op. No. 312.[13] That Advisory Opinion specifically determines that a Proposition 65 warning is an implied direction for use, and hence, labeling within the meaning of FHSA, because "it conveys the information that, in using the product, steps should be taken to minimize or eliminate exposure." App. D at 42a.

The "principle of deference to administrative interpretations" has been consistently followed by the Supreme Court, but was totally ignored by the court of appeals in this case. *Chevron U.S.A. Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837, 844 (1984). It is well settled that "considerable weight should be accorded to an executive department's construction of a statutory scheme it is entrusted to administer." *Id.* (footnote omitted). If a court

> determines Congress has not directly addressed the precise question at issue, *the court does not simply impose its own construction on the statute*, as would be necessary in the absence of an administrative interpretation. Rather, if the statute is silent or ambiguous with respect to the specific issue, *the question for the court is whether the agency's answer is based on a permissible construction of the statute.*

Id. at 843 (emphasis added) (footnote omitted). Because the court of appeals failed to address the question of whether CPSC's interpretation is a permissible construction of its own statute, the court's FHSA preemption analysis is hopelessly flawed, and this Court should grant review.

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[13] By regulation, CPSC's General Counsel has responsibility to provide "written advisory opinions interpreting the acts the Commission administers." 16 C.F.R. § 1000.7(a) (1992). Petitioner requested the court of appeals to take judicial notice of CPSC Advisory Opinion No. 312. By Order dated March 27, 1991, the motions panel deferred the request for judicial notice to the merits panel and permitted Petitioner to address the Advisory Opinion in its briefs, subject to a possible later order to strike. To the best of Petitioner's knowledge, the merits panel took no action regarding the request to take judicial notice.

The court of appeals also erroneously found that "Proposition 65 warnings are not necessarily nonidentical to the warnings required under FHSA." *Allenby*, App. A at 18a. While FHSA does allow some discretion on wording, the court's expansive interpretation of "identical" would authorize fifty different sets of state warnings for each hazard regulated under FHSA. This danger is underscored by the court's suggestion that the phrase " 'Warning, this product contains materials known to the *State of California* to cause cancer' " would comply with both FHSA and Proposition 65. *Id.* (emphasis added). While that California-specific phrase might work for a product sold in California, it would create confusion and uncertainty, and impair the credibility of the entire FHSA label, for consumers who purchase the identically labeled product in any other State. Incorporating *even one* state-specific warning onto the label of a consumer product—and under the court's scenario, there potentially could be fifty state-specific warnings all crammed onto the same label—would obstruct the national uniformity and integrity of label warnings that Congress intended FHSA and its preemption provision to achieve.

CONCLUSION

The petition for a writ of certiorari should be granted.

Respectfully submitted,

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APPENDICES

APPENDIX A

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

No. 90-16485

D.C. No. CV-90-00211-FMS OPINION

CHEMICAL SPECIALTIES MANUFACTURERS ASSOCIATION, INC.,
Plaintiff-Appellant,

v.

CLIFFORD L. ALLENBY; JOHN K. VAN DE KAMP, Esq.,
Defendants-Appellees.

Appeal from the United States District Court
for the Northern District of California
Fern M. Smith, District Judge, Presiding

Argued and Submitted
December 12, 1991—San Francisco, California

Filed March 11, 1992

Before: Procter Hug, Jr., Cynthia Holcomb Hall and Diarmuid F. O'Scannlain, Circuit Judges.

Opinion by Judge Hug

Charles A. O'Connor, III, McKenna & Cuneo, Washington, D.C., for the plaintiff-appellant.

Edward G. Weil and Clifford Rechtschaffen, Deputy Attorneys General, Oakland, California, for the defendants-appellees.

OPINION

HUG, Circuit Judge:

Chemical Specialties Manufacturers Association, Inc. ("CSMA") filed this action below seeking a declaratory judgment that the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA"), 7 U.S.C. §§ 136-136y (1988), and the Federal Hazardous Substances Act ("FHSA"), 15 U.S.C. §§ 1261-1277 (1988), preempt Proposition 65 warning requirements. The State of California filed an opposition. The district court found that no genuine issues of material fact existed, and entered a Memorandum-Decision and Order on September 11, 1990, granting the State of California's motion for summary judgment. This appeal followed and we affirm.

I. *FACTS*

CSMA is a national trade association of insecticide, disinfectant, and antimicrobial product manufacturers who sell their products to consumer, institutional, and industrial users. Many of the products manufactured by CSMA members are regulated under either FIFRA or FHSA. Both FIFRA and FHSA have express preemption provisions that prohibit certain types of state regulation, including labeling requirements on products regulated under the Acts.

The California Safe Drinking Water and Toxic Enforcement Act of 1986 ("Proposition 65") requires California to list substances that it determines to be carcinogenic or reproductively toxic. Twelve months after a sub-

stance has been listed by the state, the manufacturers of products containing the listed substances must provide adequate warnings to the consuming public that their products pose a health risk. CSMA contends that the adequate warning requirements of Proposition 65, as applied to products regulated under FIFRA and FHSA, are preempted by these Acts.

II. *DISCUSSION*

A. *Standard of Review*

A decision to grant or deny a summary judgment motion is reviewed *denovo*. *Kruso v. International Tel. & Tel. Corp.*, 872 F.2d 1416, 1421 (9th Cir. 1989), *cert. denied*, 110 S. Ct. 3217 (1990); *State Farm Fire & Cas. Co., Inc. v. Martin*, 872 F.2d 319, 320 (9th Cir. 1989).

Since this is a facial challenge to Proposition 65, CSMA "must establish that no set of circumstances exists under which the Act would be valid. The fact that the [] Act might operate unconstitutionally under some conceivable set of circumstances is insufficient to render it wholly invalid . . . ." *United States v. Salerno*, 481 U.S. 739, 745 (1987); *see also California Coastal Comm'n v. Granite Rock Co.*, 480 U.S. 572, 579-80 (1987) (party making a facial challenge to state regulations based on preemption required to demonstrate "that there is no possible set of conditions [the State] could place on its permit that would not conflict with federal law—that any state permit requirement is *per se* preempted.").

There is a presumption against finding that state legislation is preempted by an act of Congress. Preemption analysis starts with the presumption that the traditional police powers of states are not displaced by federal law unless displacement was the "clear and manifest purpose of Congress." *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947); *Maryland v. Louisiana*, 451 U.S. 725, 746 (1981). "[F]ederal regulation of a field of commerce

should not be deemed preemptive of state regulatory power in the absence of persuasive reasons—either that the nature of the regulated subject matter permits no other conclusion, or that the Congress has unmistakably so ordained." *Florida Lime & Avocado Growers v. Paul*, 373 U.S. 132, 142 (1963). We have noted two practical reasons for this presumption. First, Congress has the power to make preemption clear in the first instance. Second, if the court erroneously finds preemption, the State can do nothing about it, while if the court errs in the other direction, Congress can correct the problem. *Chevron U.S.A., Inc. v. Hammond*, 726 F.2d 483, 488 (9th Cir. 1984), *cert. denied*, 471 U.S. 1140 (1985).

In particular, "regulation of health and safety matters is primarily, and historically, a matter of local concern." *Hillsborough County v. Automated Med. Labs, Inc.*, 471 U.S. 707, 719 (1985). Consequently, courts should be especially unlikely to find preemption of state laws in these areas. *See id.* Preemption analysis is governed by a three-part test. First, Congress or a federal agency may expressly preclude all state legislation in a particular field. *Jones v. Rath Packing Co.*, 430 U.S. 519, 525 (1977). Second, an intent to displace state law may be inferred from the structure and purpose of the federal statute. *Id.* Finally, state law may be preempted if it conflicts with federal law or stands as an obstacle to the achievement of federal objectives. *Silkwood v. Kerr-McGee Corp.*, 464 U.S. 238, 248 (1984).

To find that Proposition 65 is preempted under FIFRA or FHSA, this court must determine that all possible consumer product warnings that would satisfy Proposition 65 conflict with provisions of the federal statutes. This case turns on this standard. The focus of the decision below was whether point-of-sale warnings constituted "labeling" under FIFRA or "directions for use" under FHSA. The court answered both questions in the negative and granted summary judgment for the state. Since

we agree with the district court that point-of-sale warnings are neither labels nor directions for use, we reject CSMA's preemption arguments. No other Proposition 65 warning devices need be considered since point-of-sale signs are not preempted under either FIFRA or FHSA.

B. *The Statutory Background*

1. *Proposition 65*

Proposition 65 provides that "[n]o person in the course of doing business shall knowingly and intentionally expose any individual to a chemical known to the state to cause cancer or reproductive toxicity without first giving clear and reasonable warning to such individual." Cal. Health & Safety Code § 25249.6 (West 1991). To satisfy this obligation, the statute explains that:

> "Warning" within the meaning of Section 25249.6 need not be provided separately to each exposed individual and may be provided by general methods such as labels on consumer products, inclusion of notices in mailings to water customers, posting of notices, placing notices in public news media, and the like, provided that the warning accomplished is clear and reasonable.

Id. at § 25249.11(f). Proposition 65 therefore provides several methods of compliance: (1) labeling on consumer products; (2) posting notices; (3) placing notices in the news media; (4) any other method providing clear and reasonable warning of the hazard. These methods are further expanded in the safe harbor regulations promulgated by the California Health and Welfare Agency. The safe harbor regulations designate the following language as sufficient to satisfy Proposition 65: "Warning: This product contains a chemical known to the State of California to cause cancer." Cal. Code Regs. tit. 22, § 12601 (b)(4)(A) (1991). A retail outlet can comply with Proposition 65 by posting a sign in a visible place specify-

ing the products that are known to the state to cause cancer or that are reproductively toxic. Cal. Code Regs. tit. 22, § 12601(b)(3) (1991).

2. *FIFRA*

FIFRA requires the Environmental Protection Agency ("EPA") to register a pesticide before the pesticide can be sold or used. 7 U.S.C. § 136a(a) (1988). The statute and supporting regulations contain detailed requirements for registration. Basically, the requirements are that a pesticide may not be sold (with certain exceptions) unless the EPA first determines that the product's labeling contains warnings and directions for use that are "adequate to protect the public from fraud and from personal injury and to prevent unreasonable adverse effects on the environment." 40 C.F.R. §§ 156.10(i)(1)(i), 156.10(h) (1991); *see also* 40 C.F.R. §§ 156.10(a)(1)(vii), 156.10 (a)(1)(viii) (1991); 7 U.S.C. § 136a(5)(B). Once the EPA has registered a pesticide and approved its label, the manufacturer may not change the label without the EPA's prior approval.

FIFRA's preemption clause provides as follows:

> § 136v Authority of States
>
> (a) In general
>
> A State may regulate the sale or use of any federally registered pesticide or device in the State, but only if and to the extent the regulation does not permit any sale or use prohibited by this subchapter.
>
> (b) Uniformity
>
> Such State shall not impose or continue in effect any requirements for labeling or packaging in addition to or different from those required under this subchapter.

7 U.S.C. § 136v (1988). So long as additional labeling is not required, FIFRA expressly authorizes state pesticide

regulation. Other than regulating labels, states are left free to impose whatever restrictions they may wish. Consequently, a state could prohibit the sale of a pesticide within its borders even though it could not require the manufacturer of the pesticide to change the label.

Both parties to this appeal agree that Congress included the preemption provision in FIFRA to promote uniformity and ease distribution practices for chemical product manufacturers. CSMA asserts that the uniformity objective is founded on the belief that consumers traveling between states would be confused by different labels on the same products. In support of this argument, CSMA quotes the following comment from Congressman Sisk at the congressional hearings on the 1972 FIFRA amendments:

> As I understand, Mr. Ackerly [CSMA counsel], you desire what in essence, would be Federal preemption as to labeling or as to standards on household items in connection with labeling and of the word "Poison" in certain instances. I am inclined to agree with you because I do not see how else we can really inform people who do not intend to stay in the same place, and will be reading labels in other States.

Hearings Before Comm. on Agriculture, House of Representatives, 92d Cong., 1st Sess. 287 (Mar. 8, 1971). According to CSMA, the importance of a uniform labeling system under FIFRA is rooted in a concern for clarity so that consumers can easily recognize warning labels no matter which state they enter. CSMA then suggests that the point-of-sale signs required under Proposition 65 defeat this congressional purpose by requiring additional labeling that creates consumer confusion.

CSMA's argument, however, is circular. The issue before us is whether Proposition 65 requires additional product "labeling." Certainly, if we conclude that point-of-sale signs are additional labels, then those signs are

preempted by FIFRA. Citing legislative history that explains why additional labeling is preempted, however, does not address the issue of what constitutes additional labeling. The labels attached to the chemical containers remain unchanged by Proposition 65.

3. *FHSA*

FHSA requires labeling of certain consumer products intended for use in the household or by children. The central requirement of the Act is that manufacturers of hazardous products provide cautionary labels clearly indicating the hazards and providing consumers with directions for use. The amendments to the Act contain a limited preemption provision which provides as follows:

> [I]f a hazardous substance or its packaging is subject to a cautionary labeling requirement under section 2(p) or 3(b) [15 U.S.C. §§ 1261(p) or 1262 (b)] designed to protect against a risk of illness or injury associated with the substance, no State . . . may establish or continue in effect a cautionary labeling requirement applicable to such substance or packaging and designed to protect against the same risk of illness or injury unless such cautionary labeling requirement is identical to the labeling requirement under 2(p) or 3(b).

15 U.S.C. § 1261 note (b)(1)(A) (1988) (Effect Upon Federal and State Law, § (b)(1)(A), Pub. L. 94-284 § 17(a)). The preemption issues arising under FHSA are identical to those arising under FIFRA. We must similarly determine whether the point-of-sale signs that satisfy Proposition 65 fall within the preemption clause of FHSA.

C. *Whether Proposition 65 Warnings Constitute a State Requirement for Labeling that Is Preempted under FIFRA.*

1. *Express Preemption under FIFRA.*

CSMA points out that FIFRA expressly prohibits states from imposing labeling requirements that differ from those registered with EPA. CSMA then argues that the warnings required under Proposition 65 fall squarely with FIFRA's defintion of "labeling." Consequently, CSMA asserts that Proposition 65 is expressly preempted by FIFRA. We agree that additional labeling requirements would be unconstitutional under FIFRA. However, we disagree that the warning requirements of Proposition 65 constitute additional labeling.

FIFRA defines the term labeling as follows:

> § 136(p) Label and labeling
>
> (1) Label
>
> The term "label" means the written, printed, or graphic matter on, or attached to, the pesticide or device or any of its containers or wrappers.
>
> (2) Labeling
>
> The term "labeling" means all labels and all other written, printed, or graphic matter—
>
> (A) accompanying the pesticide or device at any time; or
>
> (B) to which reference is made on the label or in literature accompanying the pesticide or device. . . .

7 U.S.C. § 136(p)(2) (1988). Under this definition, Proposition 65 warnings clearly are not "labels" within the meaning of paragraph (1), since point-of-sale warnings are neither written on the pesticide nor attached to it.

The question remains, however, whether these warnings constitute "labeling" under paragraph (2) above.

CSMA argues that the point-of-sale signs constitute labeling because they are written materials that accompany the pesticide at the point of sale. It claims that since FIFRA defines labeling as "all other written, printed, or graphic matter . . . accompanying the pesticide . . . at any time," Proposition 65's warning methods all fall within this broad definition. This interpretation, however, cannot be correct.

FIFRA's definition of labeling cannot encompass every type of written material accompanying the pesticide at any time. If this were true, then price stickers affixed to shelves, sheets indicating that a product is on sale, and even the logo on the exterminator's hat would all constitute impermissible labeling.

The leading case that interprets the term "labeling" as defined by FIFRA is *New York State Pesticide Coalition, Inc. v. Jorling*, 874 F.2d 115 (2nd Cir. 1989). In *Jorling*, the Second Circuit addressed the question of whether a New York law, designed to assure public awareness of the presence of poisonous chemicals dispensed on properties, was preempted by FIFRA. Although CSMA attempts to distinguish *Jorling*, that case is nearly identical to the one now before us.

New York passed legislation that set forth notification requirements "intended to alert the public to the impending use of poisonous chemicals and to disseminate information to those who may be exposed." *Jorling*, 874 F.2d at 116. The New York law at issue required all commercial pesticide applicators to give the purchaser of the service a cover sheet providing warnings and safety information, and to post signs on the perimeter of the affected property warning people not to enter the premises for a specified number of hours. *Id.*

The *Jorling* Court interpreted the same language from FIFRA as we must now interpret, and it concluded that the posted signs did not constitute labeling. Consequently, the New York notification law was not preempted. The Court stated:

> Because the notification materials are present in some spatial and temporal proximity to the applied pesticide, it is asserted they "accompany" it. But this definition is rather strained. *"Labeling" is better understood by its relationship, rather than its proximity, to the product.*
>
> . . . FIFRA "labeling" is designed to be read and followed by the end user. *Generally, it is conceived as being attached to the immediate container of the product in such a way that it can be expected to remain affixed during the period of use.*

Jorling, 874 F.2d at 119 (emphasis added).

CSMA cites *Jorling* for the proposition that FIFRA preempts state laws that require manufacturers to provide supplemental product warning information to the end user. Yet, *Jorling* cannot possibly stand for this proposition. The issue in *Jorling* was whether the posting of signs constituted labeling, and the court held that it did not. *Id.* The court examined the common usage of the term "labeling" and concluded that it did not apply to the posted notices required under the New York State law at issue in that case. Similarly, we conclude that the term "labeling" does not apply to the point-of-sale signs required under Proposition 65. Point-of-sale signs are not attached to the immediate container of a product and will not accompany the product during the period of use.

CSMA also cites *Kordel v. United States*, 335 U.S. 345 (1948), in support of its claim that point-of-sale signs are labels. In *Kordel*, the Court held that supplemental literature provided by a drug manufacturer constituted labeling under the Federal Food, Drug and Cosmetic Act

because it advised end users on how to administer a drug. *Kordel*, however, is distinguishable from the case at hand. First, the written materials in *Kordel* were aimed at the ultimate user of the drug, not the purchaser that is targeted by Proposition 65. 335 U.S. at 348. Second, the materials at issue in *Kordel* contained directions for use, which the EPA had clearly stated must be on the label. *Id.* Finally, the context of the manufacturer's mailings in that case suggested that the manufacturer was attempting to circumvent the Act rather than supplement it. *Id.* at 350. We find no such factors present in the instant case. Consequently, *Kordel* does not apply. FIFRA does not expressly preempt Proposition 65 since point-of-sale signs do not constitute labeling under the Act.

2. *Implied Preemption under FIFRA.*

CSMA argues that Proposition 65 is impliedly preempted by FIFRA for two reasons. First, CSMA asserts that manufacturers must seek EPA approval of new labels, when Proposition 65 requires additional warnings for the pesticide, to avoid the risk of misbranding products. The argument essentially is that by supplementing the EPA-approved label to provide an additional warning, the manufacturer implicitly acknowledges that the EPA-approved label is incomplete, thereby subjecting the manufacturer to an EPA sanction for misbranding its products. Second, CSMA argues that when Proposition 65 requires additional warnings, the manufacturers must change their labels to avoid product liability suits. Although the first of these arguments is weak, the second is not.

FIFRA provides that a pesticide is misbranded if the warning on the label is insufficient to protect the public health. 7 U.S.C. § 136(q)(1)(G) (1988). As manufacturers uncover additional information about the health risks of their products, they must bring this information to the attention of the EPA and add this information to

their product labels. CSMA argues that manufacturers who are required by Proposition 65 to post point-of-sale notices become liable under FIFRA for misbranding their products. CSMA has cited no cases in support of this argument. It seems implausible that the EPA would prosecute a company for, in essence, complying with Proposition 65.

Manufacturers only become liable for misbranding when their labels are insufficient, not for posting additional warning signs as dictated by state law. If manufacturer awareness of new product risks is triggered by the State of California's list of chemicals known to cause cancer or reproductive toxicity, then the list of chemicals merely uncovers hazards that should have been uncovered by the manufacturers. The more likely scenario is that the hazards of a chemical are already known to both the manufacturer and the EPA, but that neither believes that cancer or reproductive toxicity is a likely danger. In this scenario, it seems contradictory to assert that the EPA will prosecute a company for satisfying the standards developed by the EPA but deemed insufficient by the State of California.

CSMA's second argument in support of implied preemption is that manufacturers would be obligated to change their labels when California requires additional point-of-sale warnings. Otherwise, the manufacturers would be at risk of product liability suits for inadequate warning. This argument has merit. The issue is whether manufacturers can incur tort liability for inadequate warnings on products regulated under FIFRA. If they can, then perhaps plaintiffs could argue that the Proposition 65 warnings reveal the inadequacies of the EPA approved labels. Proposition 65 does have an express provision, however, that the warnings shall not be construed to establish exposure levels for any other regulatory purpose. Cal. Code Regs. tit. 22, §§ 12701(d), 12801(e) (1991).

Proposition 65 neither expressly nor impliedly requires additional product labeling. Consequently, manufacturers need not feel pressure to apply for EPA approval of label changes so that they can comply with Proposition 65. Point-of-sale signs are sufficient to satisfy the California requirements. Whether these signs create legitimate fears of product liability suits in other states for failing to warn of the dangers listed on the point-of-sale warnings in California, however, merits discussion. CSMA makes a good point when it claims that no manufacturer wants to face a jury in a defective labeling case arguing that a cancer, reproductive or developmental hazard warning not given in the forum state was given in California only to comply with Proposition 65. The argument, however, fails for two reasons. First, it is not clear whether plaintiffs can sue for defective labeling of products regulated by FIFRA. Second, even if they could, a point-of-sale warning required by Proposition 65 is not an admission of liability.

The case law is split on whether plaintiffs can sue manufacturers for defective labeling of products regulated by FIFRA. The argument against product liability suits for inadequate labeling is strong. State tort liability holds manufacturers liable for failing to include an adequate warning on the product's *label.* Since FIFRA expressly preempts additional state *labeling* requirements, the tort suits could circumvent the preemption clause by effectively requiring additional labeling to avoid tort liability even though the states do not expressly require the additional labeling.

In *Fitzgerald v. Mallinckrodt, Inc.*, 681 F. Supp. 404 (E.D. Mich. 1987), the court did not allow a product liability suit for inadequate labeling of a product regulated by FIFRA. The court stated:

> Where the federal government has preempted any state regulation, there can be no recovery in tort. Allowing recovery under state tort law where Con-

> gress has preempted state law would effectively authorize the state to do through the back door exactly what it cannot through the front. FIFRA expressly provides that no state may impose "*any* requirement for labeling or packaging *in addition to or different from* those required under this Act." 7 U.S.C. § 136v(b).

681 F. Supp. at 407. Other district courts finding that FIFRA preempts state tort claims for inadequate labeling include *Kennan v. Dow Chem. Co.*, 717 F. Supp. 799 (M.D. Fla. 1989), and *Fisher v. Chevron Chem. Co.* 716 F. Supp. 1283 (W.D. Mo. 1989).

An equal weight of authority, however, suggests that product liability claims for inadequate warnings are not preempted by FIFRA. Cases finding no preemption include *Arkansas Platte & Gulf Partnership v. Van Waters & Rogers, Inc.*, 748 F. Supp. 1474 (D. Colo. 1990); *Stewart v. Ortho Consumer Products*, 1990 WL 36129 (E.D. La. 1990); *Cox v. Velsicol Chem. Corp.*, 704 F. Supp. 85 (E.D. Pa. 1989); *Roberts v. Dow Chem. Co.*, 702 F. Supp. 195 (N.D. Ill. 1988).

Only two federal appellate courts have addressed the issue and these two cases are split as well. In *Ferebee v. Chevron Chem. Co.*, 736 F.2d 1529 (D.C. Cir.), *cert. denied*, 469 U.S. 1062 (1984), the D.C. Circuit held that state common law tort suits were not preempted by FIFRA. However, in *Papas v. The Upjohn Co.*, 926 F.2d 1019 (11th Cir. 1991), *petition for cert. filed sub nom.*, 60 U.S.L.W. 3016, 3053 (U.S. May 29, 1991) (No. 90-1837), the Eleventh Circuit held that state tort suits were preempted. The great split in authority is important to illustrate that even when the consequences of state action clearly pressure companies to change their FIFRA labels, there is no consensus on whether the state action is preempted. In the instant case, however, there would be no need for companies to change their labels to comply with Proposition 65, unlike the need to change labels in order

to avoid state tort liability. Whether or not product liability suits for defective labeling should be permitted, we do not believe Proposition 65 in any way pressures manufacturers to affix additional labels to the containers of their products. Consequently, the argument for implied preemption is not persuasive.

3. *Frustration of Congressional Purpose.*

For purposes of preemption analysis, CSMA must show a physical impossibility of complying with both Proposition 65 and FIFRA before succeeding on a claim that Proposition 65 is preempted on this theory. The Supreme Court has stated that the proper approach is to "reconcile the operation of both statutory schemes with one another rather than holding [that one has been] completely ousted." *Ray v. Atlantic Richfield Co.*, 435 U.S. 151, 183 (1978) (quotation marks omitted). *See also Florida Lime*, 373 U.S. at 152; *California Coastal Comm'n*, 480 U.S. at 581. Since CSMA has acknowledged the possibility of complying with both Proposition 65 and FIFRA, we need not consider whether Proposition 65 frustrates congressional purpose.

D. *Whether Proposition 65 Warnings Constitute a State Requirement for Labeling that is Preempted under FHSA.*

CSMA argues that FHSA § 17(b) expressly preempts all state mandated precautionary labeling that is not identical to that required by the Act. This is correct. FHSA § 17(b)(1)(A) provides as follows:

> [N]o State . . . may establish or continue in effect a cautionary labeling requirement applicable to such substance or packaging and designed to protect against the same risk of illness or injury unless such cautionary labeling requirement is identical . . . .

15 U.S.C. § 1261 note (1988) (Effect Upon Federal and State Law, § (b)(1)(A), Pub. L. 94-284 § 17(a)). Under

the FHSA, however, "all accompanying literature where there are directions for use, written or otherwise" is defined as cautionary labeling, 15 U.S.C. § 1261(n)(2) (1988). Accompanying literature is defined as follows:

> [A]ny placard, pamphlet, booklet, book, sign, or other written, printed, or graphic matter or visual device that provides directions for use, written or otherwise, and that is used in connection with the display, sale, demonstration, or merchandising of a hazardous substance intended for . . . use in the household or by children.

16 C.F.R. § 1500.3(c)(9) (1991). CSMA's contention that Proposition 65 point-of-sale warnings fall within this definition is implausible for two reasons. First, Proposition 65 warnings are not "directions for use," and second, the warnings are not necessarily nonidentical.

CSMA creates several strained analogies to make the argument that Proposition 65 warnings are directions for use, and therefore constitute labeling under FHSA. For example, CSMA claims that Proposition 65 warnings contain both a signal word and a statement of principle hazard: Warning, this product contains a chemical known to the State of California to cause cancer. The argument is founded upon the misconception that since this warning impliedly directs the consumer to handle the product so as to avoid or minimize direct exposure, the warning is a direction for use. Basically, CSMA argues that since Proposition 65 warnings of cancer or reproductive toxicity convey information about the product's dangers and the need to use the product cautiously, they are directions for use. We do not believe Congress intended such a broad reading of that term.

During the trial below, Judge Smith illustrated the nonsensical reading CSMA gives to the term "directions for use" when she noted during oral argument that a sign stating "this product may cause birth defects:"

> [D]oesn't tell you whether it's going to cause defects if you pour it on your feet, or if you drink it, or if you poke it in your ear, it just says that it may cause birth defects. How is that a direction for use?

Such a warning cannot, by definition, be a direction for use. *See Burch v. Amsterdam Corp.*, 366 A.2d 1079, 1086 (D.C. 1976); *Jorling*, 874 F.2d at 119.

As the State points out, Congress more likely had a common sense definition of the term "directions for use," such as how much of a detergent to use, or how long a paint solvent should be mixed. CSMA's argument that Proposition 65 warnings constitute directions for use was rejected below as counter to the plain meaning of the term. The argument simply does not comport with common sense.

Furthermore, Proposition 65 warnings are not necessarily nonidentical to the warnings required under FHSA. FHSA does not require any specific language in its warnings. The Act merely requires (1) that labels contain the signal word "WARNING" or "CAUTION" and (2) words which describe the potential hazard. Consequently, a message such as the following could comply with both Proposition 65 and FHSA: "Warning, this product contains materials known to the State of California to cause cancer."

Finally, we see no congressional purpose frustrated by Proposition 65. Congress apparently sought to balance its concern for a national safety standard with its desire for the states to promulgate their own sales and warning requirements. The legislative history makes this clear:

> This preemption scheme is designed to meet the competing interests of those who view Federal requirements as merely minimum standards and those who would opt for uniform national requirements.

S. Rep. No. 94-251, 94th Cong., 2d Sess. (1976), *reprinted in* 1976 U.S. Code Cong. & Admin. News 993, 1004. *See*

also CSMA v. Lowery, 452 F.2d 431, 438 (2d Cir. 1971). On the one hand, a national safety standard would ease the burden of compliance for chemical product manufacturers by relieving them from the burden of complying with fifty-one separate regulatory schemes promulgated by each state and the federal government. On the other hand, such a standard would take police powers away from the states who best know how to serve the interests of their citizenry. The preemption clause in FHSA balances these competing concerns by leaving cautionary labeling requirements to the federal government while allowing states to regulate the sale and use of hazardous chemicals. Proposition 65 warnings do not constitute cautionary labeling preempted by FHSA.

AFFIRMED.

APPENDIX B

UNITED STATES DISTRICT COURT
N.D. CALIFORNIA

Nos. C 90-0211 FMS, C 89-0332 FMS

CHEMICAL SPECIALTIES MANUFACTURERS ASSOCIATION, INC.,

Plaintiff,

v.

CLIFFORD ALLENBY,

Defendant.

Sept. 13, 1990

Charles A. O'Connor, III, Anthony C. Ching and Donna G. Diamon, McKenna, Conner & Cuneo, Los Angeles, Cal., for plaintiff; Stephen S. Kellner, Chemical Specialties, Washington, D.C., of counsel.

John K. Van de Kamp, Clifford Rechtschaffen, Edward Weil and Craig Thompson, Oakland, Cal., for defendant.

ORDER GRANTING AND DENYING CROSS-MOTIONS FOR SUMMARY JUDGMENT

FERN M. SMITH, District Judge.

Plaintiff, Chemical Specialties Manufacturing Association (CSMA) is a trade association whose members manufacture a variety of chemical specialty products. Plaintiff filed an action for declaratory judgment in the South-

ern District, seeking a ruling that California's Proposition 65 (Prop 65) warning requirements are preempted by two federal statutes, the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. § 136 *et seq.*, and the Federal Hazardous Substances Act (FHSA), 15 U.S.C. § 1261 *et seq.* The action was transferred from the Southern to the Eastern District and eventually transferred here soon after this Court granted partial summary judgment for defendant in the related case, *D-Con v. Allenby*, C 89 0332.

Pending before the Court are cross-motions for summary judgment on both the FIFRA and FHSA preemption issues. Plaintiff fails to adequately address this Court's decision in *D-Con v. Allenby*, 728 F.Supp. 605 (N.D.Cal.1989), wherein this Court found that, while FIFRA preempts state pesticide labeling requirements (which defendant conceded), it expressly permits state regulation of pesticide sale and use. Some of the Prop 65 warning methods deemed "safe harbor" methods by the California Health and Welfare Agency, *see* 22 CCR § 12601 *et seq.*, do not constitute "labeling" under FIFRA. Accordingly, the Court held Prop 65 not preempted by FIFRA and granted partial summary judgment in favor of defendant.

Given the earlier ruling on an identical challenge, and the fact that this plaintiff fails to raise any facts or law not previously considered by the Court, defendant's cross-motion for summary judgment as to FIFRA preemption is GRANTED and plaintiff's motion DENIED. The Court incorporates by reference its ruling in *D-Con v. Allenby*, 728 F.Supp. 605. The FHSA preemption issue is addressed below.

The Federal Hazardous Substances Act

The FHSA regulates interstate distribution and sales of hazardous consumer products which are intended for use or are packaged in a form suitable for use in the

household or by children. It also gives the Consumer Product Safety Commission (CPSC), which administers the Act, authority to ban hazardous substances when necessary to protect public health and safety. No overlap exists between the products regulated by the FHSA and those regulated by FIFRA. Unlike FIFRA, the FHSA does not require manufacturers to use a particular, federally approved label; instead the FHSA requires the use of certain warning words (e.g., "caution" or "danger") and allows the manufacturer to decide on the specific warning language.

The FHSA preempts state cautionary label requirements.[1] The statute defines labeling as follows:

> The term "label" means a display of written, printed, or graphic matter upon the immediate container of any substance or . . . upon a tag or other suitable material affixed thereto; and a requirement made by or under authority of this title that any . . . information appear on the label shall not be considered

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[1] "Except as provided . . . if a hazardous substance or its packaging is subject to a cautionary labeling requirement . . . designed to protect against a risk of illness or injury associated with the substance, no State . . . may establish or continue in effect a cautionary labeling requirement applicable to such substance or packaging and designed to protect against the same risk of illness or injury unless such cautionary labeling requirement is identical. . . ." 15 U.S.C. § 1261 note (b)(1)(A). (This is the preemption provision currently in effect; it was adopted in 1976. The earlier preemption clause is quoted in footnote 4.)

Prop 65 requires a warning against the risk of cancer or birth defects. Defendant argues that, in many instances, the FHSA cautionary label protects against a different risk of illness or injury (i.e., some harm other than cancer or birth defects). In those instances, a manufacturer presumably could comply with Prop 65 by affixing a cautionary label to the product since the label would not be "designed to protect against the same risk of injury or illness." The Court need not decide whether defendant's reading of the statute is correct; even if a manufacturer could not comply with both Prop 65 and the FHSA via package labeling, other Prop 65 warning methods remain available to it.

> to be complied with unless such . . . information also appears (1) on the outside container or wrapper . . . and (2) on all accompanying literature *where there are directions for use*, written or otherwise.

15 U.S.C. § 1261(n) (emphasis added).[2]

Plaintiff argues that only direct package labeling will satisfy the Prop 65 "clear and reasonable" warning requirement. As previously stated by this Court, determinations as to what does and what does not meet the requirements of Prop 65 are best made by state courts. Plaintiff also contends that the alternative warning methods deemed "safe harbor" provisions by the California Health and Welfare Agency (e.g., point-of-sale signs and telephone information services) are all "labeling" within the meaning of the FHSA.

Defendants argue that the Court need only find that *any* form of warning authorized by the existing regulations falls outside the scope of preempted "labeling" in

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[2] Plaintiff relies on this portion of the statute to support the argument that *all* "accompanying literature" (such as shelf-labeling and other point-of-sale information) constitutes "labeling" under the FHSA. In addition to advancing a strained construction of that language, plaintiff would have the Court read the phrase "where there are directions for use" right out of the statute. That phrase appears repeatedly in reference to "accompanying literature." *See* 16 C.F.R. 1500.3(c)(9) (accompanying literature includes "any placard, pamphlet, booklet, book, sign, or other written or graphic matter or visual device *that provides directions for use* . . . and that is used in connection with the display, sale, demonstration or merchandising of a hazadous substance . . .); 40 C.F.R. § 1500.125 ("[w]hen any accompanying literature *includes or bears directions for use* . . . such placard pamphlet, . . . shall bear all the information required by § 2(p) of this act").

Plaintiff argues that a manufacturer could not lawfully include with its product "accompanying literature" which did not contain the required FHSA warning, even if such literature did *not* contain directions for use. That may be true. What a manufacturer may not do and what a state is preempted from requiring are not necessarily one and the same, however.

order to find Prop 65 not preempted. It is unclear whether plaintiff disagrees with that proposition. Case law squarely supports defendant's view, however. "Federal regulation of a field of commerce should not be deemed preemptive of state regulatory power in the absence of persuasive reasons—either that the nature of the regulated subject matter permits no other conclusion, or that Congress has unmistakenly so ordained." *Florida Avocado Growers v. Paul*, 373 U.S. 132, 142, 83 S.Ct. 1210, 1217, 10 L.Ed.2d 248 (1962).[3] *See also Jones v. Rath Packing Co.*, 430 U.S. 519, 525, 97 S.Ct. 1305, 1309, 51 L.Ed.2d 604 (1976) ("[W]e start with the assumption that the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress"). In this case, the nature of the regulated subject matter—health and safety—is an area traditionally left to the states.

There is little case law interpreting the term "labeling" within the meaning of the FHSA. The two cases relied upon by plaintiff were both decided prior to the Congressional amendment which narrowed the scope of the FHSA's preemption provision[4] and both dealt with state regula-

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[3] The Ninth Circuit notes two practical reasons for this presumption. First, Congress has the power to make preemption clear in the first instance. Second, if a court erroneously finds preemption, a state can do nothing; whereas if the court errs in the other direction, Congress presumably can correct the problem. *Chevron v. Hammond*, 726 F.2d 483, 488 (9th Cir.1984).

[4] The original FHSA "limited preemption amendment", adopted in 1966, declared Congress' intent to "supersede any and all laws of the States . . . insofar as they may . . . provide for cautionary labeling of any substance or article intended for household use . . . which differs from the requirements or exemptions of this Act." In 1976, Congress amended the provision and limited preemption to instances where there is a federal labeling requirement in effect and a State imposes a different labeling requirement that seeks to warn about the same hazards. (The amended clause is quoted, *supra* at footnote 1.)

tions requiring information to be printed on the product label itself. *See CSMA v. Lowery*, 452 F.2d 431 (2d Cir.1971) (New York City regulation required that certain information appear on product container and on the "carton, case, or similar bulk package" housing the product); *CSMA v. Clark*, 482 F.2d 325 (5th Cir. 1973) (local ordinance required information to be printed on the product's "container, wrapping, or other packaging"). Cases dealing with preemption of state "labeling" requirements under other, analogous federal Acts were addressed in the related case of *D-Con v. Allenby*.

The only new case cited by plaintiff is *Professional Lawn Care Association v. Village of Milford*, 909 F.2d 929 (1990, 6th Cir.). *Lawn Care* concerns a challenge to a local ordinance (not a state statute) regulating pesticide use. The Court held that § 24(a) of FIFRA, which expressly allows *state* regulation of pesticide sale and use, extended only to states, not localities. The ordinance was deemed preempted for that reason.

Plaintiff argues that Prop 65 may require warnings in instances where federal law does not so require. That is not disputed. In *Avocado Growers*, 373 U.S. at 132, 83 S.Ct. at 1210-13, the Supreme Court considered divergent state and federal requirements and found "no impossibility of dual compliance." Because there existed "no inevitable collision between the two schemes of regulation, despite the dissimilarity of the standards," the Court declined to find the California law at issue there invalid under the Supremacy Clause.[5] *Id.* 373 U.S. at 143, 83 S.Ct. at 1218. Accordingly, the fact that California may impose stricter standards than does the FHSA does not invalidate the California regulatory scheme.[6]

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[5] California law set the standard for maturity of avocadoes at more than 8% oil by weight, whereas avocadoes were deemed mature under federal law at over 7% oil by weight.

[6] In fact, defendant notes that nothing in the FHSA prevents manufacturers from voluntarily affixing warning labels on products for which labels are not required under federal law.

Finally, plaintiff submits declarations from various individuals, one former EPA Administrator and a number of industry "health and safety" experts, discussing the conflicts between the federal and state laws and the danger presented by "overlabeling." The declarants express concern that additional warnings, such as those required by Prop 65, will reduce consumer confidence in EPA approved labels, thus undermining the FIFRA and FHSA scheme. None of these declarants have any expertise in the area of human psychology. Even if they were absolutely correct, however, Congress clearly did not intend to occupy this entire area of regulation, as evidenced by the fact that states are expressly allowed certain functions under both FIFRA and FHSA. No evidence shows the impossibility of complying with both the federal and state statutes; therefore, Prop 65 is not preempted.

Plaintiff's motion for partial summary judgment is DENIED; defendant's motion is GRANTED.

SO ORDERED.

APPENDIX C

STATUTORY PROVISIONS AND REGULATIONS INVOLVED

7 U.S.C. § 136(p)(1), (p)(2) (1988)

§ 136. Definitions

For purposes of this subchapter—

(p) Label and labeling

(1) Label

The term "label" means the written, printed, or graphic matter on, or attached to, the pesticide or device or any of its containers or wrappers.

(2) Labeling

The term "labeling" means all labels and all other written, printed, or graphic matter—

(A) accompanying the pesticide or device at any time; or

(B) to which reference is made on the label or in literature accompanying the pesticide or device, except to current official publications of the Environmental Protection Agency, the United States Departments of Agriculture and Interior, the Department of Health and Human Services, State experiment stations, State agricultural colleges, and other similar Federal or State institutions or agencies authorized by law to conduct research in the field of pesticides.

7 U.S.C. § 136v(a), (b) (1988)

§ 136v. Authority of States

(a) In general

A State may regulate the sale or use of any federally registered pesticide or device in the State, but only if and to the extent the regulation does not permit any sale or use prohibited by this subchapter.

(b) Uniformity

Such State shall not impose or continue in effect any requirements for labeling or packaging in addition to or different from those required under this subchapter.

15 U.S.C. § 1261(f)(1)(A), (f)(2), (n) (1988)

§ 1261. Definitions

For the purposes of this chapter—

(f) The term "hazardous substance" means:

(1)(A) Any substance or mixture of substances which (1) is toxic, (ii) is corrosive, (iii) is an irritant, (iv) is a strong sensitizer, (v) is flammable or combustible, or (vi) generates pressure through decomposition, heat, or other means, if such substances or mixture of substances may cause substantial personal injury or substantial illness during or as a proximate result of any customary or reasonably foreseeable handling or use, including reasonably foreseeable ingestion by children.

(2) The term "hazardous substance" shall not apply to pesticides subject to the Federal Insecticide, Fungicide, and Rodenticide Act [7 U.S.C. 136 et seq.], nor to foods, drugs and cosmetics subject to the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 301 et seq.], nor to substances intended for use as fuel when stored in containers and used in the heating, cooking, or refrigeration system of a house, nor to tobacco and tobacco products, but such term shall apply to any article which is not itself a pesticide within the meaning of the Federal Insecticide, Fungicide, and Rodenticide Act but which is a hazardous substance within the meaning of paragraph (1) of this subsection by reason of bearing or containing such a pesticide.

(n) The term "label" means a display of written, printed, or graphic matter upon the immediate container of any substance or, in the case of an article which is unpackaged or is not packaged in an immediate container intended or suitable for delivery to the ultimate consumer, a display of such matter directly upon the article involved or upon a tag or other suitable material affixed thereto; and a requirement made by or under authority of this chapter that any word, statement, or other information appear on the label shall not be considered to be complied with unless such word, statement, or other information also appears (1) on the outside container or wrapper, if any there be, unless it is easily legible through the outside container or wrapper and (2) an all accompanying literature where there are directions for use, written or otherwise.

15 U.S.C. § 1261 note (b)(1)(A) (1988)

EFFECT UPON FEDERAL AND STATE LAW

Pub. L. 86-613, § 18, formerly § 17, July 12, 1960, 74 Stat. 380, as amended Pub. L. 89-756, § 4(a), Nov. 3, 1966, 80 Stat. 1305; renumbered and amended Pub. L. 91-113, § 4(a), (b)(1), Nov. 6, 1969, 83 Stat. 189, 190; Pub. L. 94-284, § 17(a), May 11, 1976, 90 Stat. 510, provided that:

"(b)(1)(A) Except as provided in paragraphs (2) and (3), if a hazardous substance or its packaging is subject to a cautionary labeling requirement under section 2(p) or 3(b) [subsec. (p) of this section or section 1262 (b) of this title] designed to protect against a risk of illness or injury associated with the substance, no State or political subdivision of a State may establish or continue in effect a cautionary labeling requirement applicable to such substance or packaging and designed to protect against the same risk of illness or injury unless such cautionary labeling requirement is identical to the labeling requirement under section 2(p) or 3(b) [subsec. (p) of this section or section 1262(b) of this title].

16 C.F.R. § 1500.3(c)(9) (1992)

PART 1500—HAZARDOUS SUBSTANCES AND ARTICLES; ADMINISTRATION AND ENFORCEMENT REGULATIONS

§ 1500.3 Definitions.

(c) *Certain statutory definitions interpreted, supplemented, or provided with alternatives.* The following items interpret, supplement, or provide alternatives to definitions set forth in section 2 of the act (and restated in paragraph (b) of this section):

(9) In the definition of "label" in section 2(n) of the act (restated in paragraph (b)(12) of this section), a provision stipulates that words, statements, or other information required to be on the label must also appear on all accompanying literature where there are directions for use, written or otherwise. To make this provision more specific, "accompanying literature" is interpreted to mean any placard, pamphlet, booklet, book, sign, or other written, printed, or graphic matter or visual device that provides directions for use, written or otherwise, and that is used in connection with the display, sale, demonstration, or merchandising of a hazardous substance intended for or packaged in a form suitable for use in the household or by children.

Cal. Code Regs. tit. 22, § 12601(b) (1991)

Article 6. Clear and Reasonable Warnings

§ 12601. Clear and Reasonable Warnings.

(b) Warnings for consumer products exposures which include the methods of transmission and the warning messages as specified by this subdivision shall be deemed to be clear and reasonable. A "consumer products exposure" is an exposure which results from a person's acquisition, purchase, storage, consumption, or other reasonably foreseeable use of a consumer good, or any exposure that results from receiving a consumer service.

(1) The warning may be provided by using one or more of the following methods singly or in combination:

(A) A warning that appears on a product's label or other labeling. The term "label" means a display of written, printed or graphic matter upon a product or its immediate container. The term "labeling" means any label or other written, printed or graphic matter affixed to or accompanying a product or its container or wrapper.

(B) Identification of the product at the retail outlet in a manner which provides a warning. Identification may be through self labeling, signs, menus, or a combination thereof.

(C) A system of signs, public advertising identifying the system and toll-free information services, or any other system, that provides clear and reasonable warnings.

(D) For alcoholic beverages, including, without limitation, beer, malt beverages, wine and distilled spirits:

1. Primarily intended for consumption off the premises where sold or distributed:

(i) at least one notice or sign, no smaller than 10 inches wide by 10 inches high, and bearing the warning message set forth in paragraph (4)(E) of this subsection; or

(ii) at least one horizontal strip marker no smaller than 10½ inches wide by 1¼ inches high, and bearing the warning message set forth in paragraph (4)(E) of this subsection; or

(iii) a notice no smaller than 5 inches by 5 inches, and bearing the warning message set forth in (4)(E) of this subsection.

(iv) If signs 10 inches high by 10 inches wide are used, the word "warning" shall be centered three-quarters of an inch from the top of the sign in ITC Garamond bold condensed type face all in one-inch capital letters. Three-sixteenths of an inch from the base of the word "warning" shall be a line extending from left to right across the width of the sign one-sixteenth of an inch in thickness. Centered one-half inch below the line shall be the body of the warning message in 36/50 ITC Garamond bold condensed type face with the intial letter of each word, other than the conjunctive "and," capitalized. For the body of the warning message, left and right margins of at least one-half of an inch, and a bottom margin of at least one-half inch shall be observed. Larger signs shall bear substantially the same proportions of type size and spacing to sign dimension as the sign 10 inches high by 10 inches wide.

(v) If the 10½ inch by 1¼ inch horizontal strip markers are used, the word "WARNING," punctuated by a colon, shall be justified left and located three-sixteenths of an inch from the top of the strip notice in ITC Garamond bold condensed type face all in capital letters measuring eleven sixteenths of an inch in height. Three thirty-seconds of an inch from the base of the word "WARNING" shall be a line extending from left to right across the width of the word "WARNING" and the punctuating colon one thirty-second of an inch in thickness. Located one-fourth of an inch from the top and one-fourth of an inch from the bottom of the strip notice, and to the immediate right of the word "WARNING," shall be the body of the warning message in 12/16 point ITC Gara-

mond bold condensed type face with the initial letter of each word, other than the conjunctive "and," capitalized. The word "WARNING" shall be one-half inch from the left edge of the strip notice and the requisite warning message shall extend to within one-half inch from the right edge.

(vi) If the 5 inch by 5 inch signs are used, they shall bear substantially the same proportions of type size and spacing to sign dimension as the sign 10 inches high by 10 inches wide, with both the word "WARNING" and the warning text set in white on a contrasting red background.

(vii) Such sign or notice shall be placed in the retail establishment so as to assure that it is readable and likely to be read either at each retail point of sale or each point of display. Such sign or notice shall be placed either at all retail points of sale or all points of display, but need not be placed at both. If 10 inch by 10 inch signs or notices are placed at the point of display, each shall be placed no more than ten feet from any alcoholic beverage container and in a manner associating the sign or notice with the display. If horizontal strip notices are used, they shall be placed at ten foot intervals horizontally along the display. If a 5 inch by 5 inch sign is used, it shall be conspicuously placed at each retail point of sale (e.g., checkout counter, cash register, cash box) so that it is likely to be read and understood during the sales transaction.

(viii) All measurements specified or referred to in paragraphs (iv), (v) and (vi), above, are not required to be precisely accurate.

2. Provided for consumption on the premises at tables served by food or beverage persons, or sold or distributed through over the counter service;

(i) a notice or sign displayed at each of the tables where alcoholic beverages are served or may be con-

sumed at least 5 inches high by 5 inches wide bearing substantially the same type face and substantially the same proportion of type size and spacing to sign dimension as described in paragraph (D)1. (vi); or

(ii) the warning message set forth in paragraph (4)(E) of this subdivision, placed upon a menu or list in association with the alcoholic beverages listed thereon and served at such premises, or if alcoholic beverages are not listed thereon, on any menu or list provided to patrons in association with the listing of food or beverages offerings, in type size and design, such that the text is conspicuous and likely to be read prior to consumption of alcoholic beverages or,

(iii) at least one 10 inch by 10 inch sign, meeting the specifications set forth in paragraph (D)1. (iv) of this subsection, placed so that it is readable and likely to be read by patrons as they enter each public entrance to the establishment. If the establishment does not have clearly defined physical boundaries delineating those areas where, by permit or license, alcoholic beverages are served, the 10 inch by 10 inch sign shall be posted so that it is readable and likely to be read by patrons as they enter the area or areas where, by permit or license, alcoholic beverages are served; and

(iv) If sold or distributed through over-the-counter service, at least one sign, meeting the specifications set forth in paragraph (D)1. (iv) of this subsection, placed in the retail establishment so that the warning message is, prior to the consumption of alcoholic beverages, readable and likely to be read from all counter locations available to the public. Therefore, a retail establishment providing a warning pursuant to the preceding sentence, also would be required to provide a warning in accordance with either paragraph 2.(i), 2.(ii) or 2.(iii) of this subsection.

3. For premises which are specially licensed to sell and serve alcoholic beverages both on and off the licensed premises (e.g., in facilities that offer both "tasting" and retail sales), the off-sale portion of the premises shall comply with the provisions of subsection (D)1, above, and the portion of the premises where alcoholic beverages are served shall comply with the provisions of subsection (D)2, above.

4. For alcoholic beverages sold or distributed to consumers through the mail or package delivery services, warnings may be provided by incorporating or placing the warning message set forth in paragraph (4)(E) on or in the shipping container or delivery package in such a manner so that the warning message is likely to be read by the recipient prior to consumption of the alcoholic beverage(s).

5. All signs or notices referred to in subsections (D)1., (D)2. and (D)3., above, shall be displayed so that they are clearly visible under all lighting conditions normally encountered during business hours.

(2) To the extent practicable, warning materials such as signs, notices, menu stickers, or labels shall be provided by the manufacturer, producer, or packager of the consumer product, rather than by the retail seller. For alcoholic beverages, the placement and maintenance of the warning shall be the responsibility of the manufacturer or its distributor at no cost to the retailer, and any consequences for failure to do the same shall rest solely with the manufacturer or its distributor, provided that the retailer- does not remove, deface, or obscure the requisite signs or notices, or obstruct, interfere with, or otherwise frustrate the manufacturer's reasonable efforts to post, maintain, or periodically replace said materials. For prescription drugs, the labeling approved or otherwise provided under federal law and the prescriber's accepted practice of obtaining a patient's informed consent shall be deemed to be a clear and reasonable warning.

(3) The warnings provided pursuant to paragraphs (1)(A) and (1)(B) shall be prominently placed upon a product's label or other labeling or displayed at the retail outlet with such conspicuousness, as compared with other words, statements, designs, or devices in the label, labeling or displays as to render it likely to be read and understood by an ordinary individual under customary conditions of purchase or use.

(4) The warning message must include the following language:

(A) For consumer products that contain a chemical known to the state to cause cancer:

"WARNING: This product contains a chemical known to the State of California to case cancer."

(B) For consumer products that contain a chemical known to the state to cause reproductive toxicity:

"WARNING: This product contains a chemical known to the State of California to cause birth defects or other reproductive harm."

(C) For food, other than alcoholic beverages, sold, served, or otherwise provided in food facilities, as defined in Health and Safety Code section 27521(a), which is intended for immediate consumption:

"WARNING: Chemicals known to the State of California to cause cancer, or birth defects or other reproductive harm may be present in foods or beverages sold or served here."

(D) For fresh fruits, nuts and vegetables:

"WARNING: This product may contain a chemical known to the State of California to cause cancer, or birth defects or other reproductive harm."

(E) For alcoholic beverages, including, without limitation, beer, malt beverages, wine and distilled spirits:

"WARNING: Drinking Distilled Spirits, Beer, Coolers, Wine and Other Alcoholic Beverages May Increase Can-

cer Risk, and, During Pregnancy, Can Cause Birth Defects."

(5) A person in the course of doing business, who manufactures, produces, assembles, processes, handles, distributes, stores, sells or otherwise transfers a consumer product which he or she knows to contain a chemical known to the state to cause cancer or reproductive toxicity in an amount which requires a warning shall provide a warning to any person to whom the product is sold or transferred unless the product is packaged or labeled with a clear and reasonable warning.

Cal. Health & Safety Code § 25249.6 (West Supp. 1992)

§ 25249.6 Required warning before exposure to chemicals known to cause cancer or reproductive toxicity

No person in the course of doing business shall knowingly and intentionally expose any individual to a chemical known to the state to cause cancer or reproductive toxicity without first giving clear and reasonable warning to such individual, except as provided in Section 25249.10.

(Added by Initiative Measure, Nov. 4, 1986.)

Cal. Health & Safety Code § 25249.11(f) (West Supp. 1992)

§ 25249.11 Definitions

For purposes of this chapter:

(f) "Warning" within the meaning of Section 25249.6 need not be provided separately to each exposed individual and may be provided by general methods such as labels on consumer products, inclusion of notices in mailings to water customers, posting of notices, placing notices in public news media, and the like, provided that the warning accomplished is clear and reasonable. In order to minimize the burden on retail sellers of consumer products including foods, regulations implementing Section 25249.6 shall to the extent practicable place the obligation to provide any warning materials such as labels on the producer or packager rather than on the retail seller, except where the retail seller itself is responsible for introducing a chemical known to the state to cause cancer or reproductive toxicity into the consumer product in question.

(Added by Initiative Measure, Nov. 4, 1986.)

APPENDIX D

Advisory Op. No. 312

U.S. CONSUMER PRODUCT SAFETY COMMISSION
WASHINGTON, D.C. 20207

Office of the General Counsel

March 6, 1991

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Gentlemen:

This is in response to a request from the Chemical Specialties Manufacturers Association for an advisory opinion from the Consumer Product Safety Commission addressing the following question.

> Do the signal word and principal statement of hazard "WARNING: This product contains a chemical known to the state to cause cancer (or birth defects)," when used in connection with the sale (*e.g.*, shelf sign, brochure, display sign) of an FHSA hazardous substance constitute "directions for use" pursuant to FHSA § 2(n), 15 U.S.C. § 1261(n), thereby rendering them accompanying literature subject to the labeling requirements of FHSA § 2(p), 15 U.S.C. § 1261(p)?

This office has also received correspondence from the State of California concerning how the Commission interprets the Federal Hazardous Substances Act ("FHSA") as it concerns issues raised by California's Safe Drinking Water and Toxic Enforcement Act (Proposition 65). Because the answer to CSMA's question is relevant to these concerns, this letter is also being sent to the California Department of Justice.

The FHSA provides a comprehensive scheme for ensuring that hazardous substances intended for use in the household or by children bear cautionary labeling. Included within the FHSA's definition of hazardous substances are those substances that are toxic because they present a risk of cancer or other types of chronic toxicity, such as reproductive toxicity. CPSC General Counsel's Advisory Opinion No. 309 at 7 (March 19, 1987). Thus, a product would be regulated under the FHSA if (1) it is intended or packaged in a form suitable for use in the household or by children and (2) if the exposure to the product creates a significant risk of cancer or reproductive toxicity as a proximate result of any customary or reasonably foreseeable handling or use.

Section 2(p)(1) of the FHSA requires hazardous substances to bear certain types of label messages. Included within the types of labeling required are:

1. The name of each component that contributes substantially to the hazard,

2. A signal word (in the case of chronic hazards, "WARNING" or "CAUTION"),

3. An affirmative statement of the hazard or hazards (*e.g.*, "Vapor harmful"),

4. Precautionary measures describing the action(s), to be taken or avoided,

5. Any necessary or appropriate instruction for first aid treatment,

6. Any required instruction for special handling or storage of the package, and

7. The statement "Keep out of the reach of children," or its equivalent.

FHSA Sec. 2(p)(1)(B), (D)-(J)(i), 15 U.S.C. § 2(p)(1)(B), (D)-(J)(i). Except for the signal word, the FHSA generally does not require particular label language and permits manufacturers to decide on the specific language. (In addition, the Commission may, by rule, require different or additional labeling where required by a special hazard presented by the substance. Section 3(b) of the FHSA, 15 U.S.C. § 1262(b). Where labeling cannot adequately protect the public, the Commission may ban a hazardous substance. Sec. 2(q)(1)(B), 15 U.S.C. § 1261(q)(1)(B).)

Section 2(n) of the FHSA defines "label." In addition to specifying that matter on the product or its container is part of the label, section 2(n) reads, in pertinent part:

> a requirement [under the FHSA] that any word, statement, or other information appear on the label shall not be considered to be complied with unless such word, statement, or other information also appears . . . (2) on all *accompanying literature where there are directions for use*, written or otherwise.

15 U.S.C. 1261(n) (emphasis added). In other words, where accompanying literature contains directions for use, it must contain *all* the cautionary labeling required on the product label by the FHSA.

The Commission's regulations specify that:

> "accompanying literature" is interpreted to mean any placard, pamphlet, booklet, book, sign, or other written, printed, or graphic matter or visual device that

> provides *directions for use*, written or otherwise, and that is used in connection with the display, sale, demonstration, or merchandising of a hazardous substance . . . .

16 C.F.R. § 1500.3(c)(9) (emphasis added). Shelf signs, brochures, and display signs are "accompanying literature" under this definition.

A warning that a product can cause cancer or birth defects is not an express direction for use. Nevertheless, it conveys the information that, in using the product, steps should be taken to minimize or eliminate exposure. Stated another way, the warning itself can also serve as a direction for use. An example of the dual function performed by statements warning of hazards a product presents is in the Commission's regulations at 16 C.F.R. § 1500.123. That section states:

> Whenever the statement of the principal hazard or hazards itself provides the precautionary measures to be followed or avoided, a clear statement of the principal hazard will satisfy the requirements of section 2(p)(1)(E) [statement of principal hazard] and
>
> (F) ["precautionary measures describing the action to be followed or avoided"] . . .

Thus, for example, a product having flammable vapors might have a statement of principal hazard, such as "FLAMMABLE," that could serve also as the required statement of action to be avoided, which, if stated separately, might read "do not use near open flame." Similarly, the statement of principal hazard "HARMFUL IF SWALLOWED" could negate the need to state additionally "for external use only." Also, the statement "VAPOR HARMFUL" could also serve instead of an additional statement to "avoid prolonged inhalation of vapors."

Therefore, although the warning quoted in your inquiry does not necessarily convey specific actions to be taken in

the use of the product, it does convey information about how the product should be used (steps should be taken to reduce exposure). Accordingly, this office views the statement as a direction for use. It follows, therefore, that signs and the like bearing such warnings are "accompanying literature containing directions for use" and thus are labeling under FHSA § 2(n). The fact that such signs are considered labeling, however, does not mean that the sign complies with any or all of the FHSA labeling requirements described above.

I trust that this information responds fully to your inquiry. Please contact me if you have further questions.

Sincerely,

/s/ Clement D. Erhardt, III
CLEMENT D. ERHARDT, III
General Counsel

(4)

Supreme Court, U.S.
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In the
SUPREME COURT OF THE UNITED STATES
October Term, 1991

No. 91-1957

CHEMICAL SPECIALTIES MANUFACTURERS ASSOCIATION,

Petitioner,

v.

STEVEN A. BOOK; DANIEL E. LUNGREN,

Respondents.

Petition for Writ of Certiorari to the
United States Court of Appeals
for the Ninth Circuit

BRIEF FOR RESPONDENTS IN OPPOSITION TO PETITION FOR WRIT OF CERTIORARI

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QUESTIONS PRESENTED

1. Whether the Ninth Circuit properly ruled that Proposition 65 point-of-sale signs and other warnings are not preempted by the specific preemption clause of the Federal Insecticide, Fungicide and Rodenticide Act which preempts additional or different state "labeling" requirements.

2. Whether the Ninth Circuit properly ruled that Proposition 65 point-of-sale signs and other warnings are not preempted by the specific preemption clause of the Federal Hazardous Substances Act which preempts nonidentical state "labeling" requirements.

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No. 91-1957

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v.

STEVEN A. BOOK; DANIEL E. LUNGREN,[1]

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BRIEF FOR RESPONDENTS IN OPPOSITION TO PETITION FOR WRIT OF CERTIORARI

OPINIONS BELOW

The opinion of the Court of Appeals (Pet. App. 1a-19a) is reported at 958 F.2d 941. The decision of the

1. Pursuant to State of California Executive Order W-15-91, on July 17, 1991, all official responsibility for the implementation of Proposition 65 that previously had been assigned to the California Health and Welfare Agency was reassigned to the Office of Environmental Health Hazard Assessment, a department within the California Environmental Protection Agency. The Interim Director of that Office is Steven A. Book, who therefore has succeeded to all responsibilities of respondent Clifford L. Allenby. Daniel E. Lungren succeeded respondent John K. Van de Kamp as Attorney General of California on January 7, 1991.

District Court for the Northern District of California (Pet. App. 20a-26a) is reported at 744 F.Supp. 934.

JURISDICTION

The judgment of the Court of Appeals was entered on March 11, 1992. The jurisdiction of this Court is invoked under 28 U.S.C. § 1254(1) (1988).

STATEMENT OF THE CASE

This case involves a facial challenge to California's Proposition 65, a voter initiative that requires businesses to provide warnings before exposing individuals to harmful levels of certain toxic chemicals. Cal. Health & Safety Code § 25249.5 *et seq.* (West Supp. 1992). Petitioner seeks declaratory and injunctive relief that all possible applications of the statute's warning requirement to pesticides and consumer products are preempted by the Federal Insecticide, Fungicide and Rodenticide Act ("FIFRA"), 7 U.S.C. § 136 *et seq.* (1980 & Supp. 1992) and the Federal Hazardous Substances Act ("FHSA"), 15 U.S.C. § 1261 *et seq.* (1982 & Supp. 1992).[2/]

Proposition 65, the Safe Drinking Water and Toxic Enforcement Act of 1986, is a California initiative statute overwhelmingly passed by a vote of the people in November of 1986. The warning requirement of the statute provides that "[n]o person in the course of doing business shall knowingly and intentionally expose any individual to a chemical known to the state to cause cancer or reproductive toxicity without first giving clear and reasonable warning to such individual." Cal. Health & Safety Code, § 25249.6.

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2. Contrary to petitioner's suggestion (Pet. 3), the complaint seeks a judgment that *all* Proposition 65 warning methods are preempted, not just point-of-sale warning requirements.

The statute does not define the term warning, but explains that:

> "Warning" within the meaning of Section 25249.6 need not be provided separately to each exposed individual and may be provided by general methods such as labels on consumer products, inclusion of notices in mailings to water customers, *posting of notices, placing notices in public news media, and the like, provided that the warning accomplished is clear and reasonable.*

Id., § 25249.11(f). (Emphasis added.)

Implementing regulations promulgated by the State further identify certain methods of providing warnings for consumer products that are deemed to comply with the statute (i.e. "safe harbors"), but also allow businesses to use other warning methods that are "clear and reasonable." Cal. Code Regs., tit. 22, § 12601(b) (1991). For consumer products, the "safe harbors" include (1) product labeling; and (2) shelf labeling, signs, menus, or a combination thereof.

FIFRA requires the Environmental Protection Agency ("EPA") to register a pesticide before it can be sold or used. 7 U.S.C. § 136a. Before registering a pesticide, EPA evaluates the data concerning the product's potential harmful effects. *Id.* § 136a (c)(2). As part of this process, all "labeling" must be submitted to EPA for its advance approval. The statute's labeling requirements are designed to assure that the product can be used without "unreasonable adverse effects on the environment." 7 U.S.C. § 136a (c)(5)(C) & (D).

The FHSA regulates consumer products that are intended for use or are packaged in a form suitable for use in the household or by children. 15 U.S.C. § 1261(p). The act's central requirement is that marketers of

consumer products that are "hazardous substances" must provide "cautionary" labels on their products. *Id.* The FHSA does not require that product labels be approved by the Consumer Product Safety Commission, ("CPSC"), which enforces the act, but leaves manufacturers free to devise their own language provided it meets the requirements of the act.

Both FIFRA and the FHSA contain narrow preemption clauses. Under FIFRA, States may regulate the sale or use of pesticides, but may not impose any different or additional "labeling" requirements. 7 U.S.C. § 136v (a) & (b). The FHSA authorizes states to ban certain products lawfully sold under federal law but precludes states from adopting nonidentical "labeling" requirements where there is a federal cautionary labeling requirement in effect. 15 U.S.C. § 1261n (b)(1)(A).

Petitioner filed this action in March, 1989. It did not allege any concrete application of Proposition 65 or even that any of its members had been required to provide a Proposition 65 warning. In the district court, both parties moved for summary judgment. The court denied Petitioner's motion and granted Respondent's cross-motion for summary judgment. *Chemical Specialties Manufacturers Ass'n* v. *Allenby*, 744 F.Supp. 934 (N.D. Cal. 1990) (hereinafter "*Allenby*").

The trial court rejected Petitioner's claim that FIFRA and the FHSA expressly preempt Proposition 65's warning requirement. It found that some Proposition 65 warning methods, including point-of-sale signs, were not "labeling" under either federal statute. Pet. App. at 21a, 22a n. 1.[3/]

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3. The court incorporated by reference its earlier decision in the related FIFRA preemption case of *D-Con* v. *Allenby*, 728 F.Supp. 605, 607 (N.D. Cal. 1990).

The district court further ruled that "[n]o evidence shows the impossibility of complying with both the federal and state statutes," and that no competent evidence supported Petitioner's assertion that Proposition 65 would undermine the goals of federal law by causing consumer confusion. Pet. App. at 26a. Finally, the Court held that "Congress clearly did not intend to occupy this entire area of regulation, as evidenced by the fact that states are expressly allowed certain functions under both FIFRA and FHSA." *Id.*

The Ninth Circuit, in a 3-0 decision, affirmed. As to express preemption, the court concluded that while FIFRA expressly preempts additional *labeling* requirements, Proposition 65's *warning* requirements do not constitute additional labeling. Pet. App. at 9a. It cited point of sale signs as one Proposition 65 warning method that was not "labeling", while leaving open the possibility that other warning methods also might be outside the scope of preempted "labeling". Pet. App. at 4a, 5a. With respect to the FHSA, the Ninth Circuit found that Proposition 65 point of sale warnings were not preempted for two independent reasons: one, they were not "labeling", as defined by federal law, and two, they were not necessarily "nonidentical" to federal requirements. Pet. App. at 17a.[4/]

The Ninth Circuit found no support in the legislative history of FIFRA or the FHSA to support Petitioner's claim that Congress intended to occupy the field of warnings for pesticides or hazardous household products, Pet. App. at 7a-8a, consistent with this Court's holding in *Wisconsin Public Intervenor v. Mortier*, 111 S.Ct. 2476 (1991) (hereinafter "*Mortier*").

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4. The court noted that since Petitioner had mounted a facial challenge to Proposition 65, it had to demonstrate "that all possible consumer product warnings that would satisfy Proposition 65 conflict with provisions of the federal statutes." Pet. App. at 4a.

Finally, the court of appeals determined that there were no actual conflicts between Proposition 65 and federal law, since Proposition 65 does not force manufacturers to alter their FIFRA labels and does not necessarily impose requirements which are "nonidentical" to those mandated by the FHSA. Pet. App. at 18a-19a.

SUMMARY OF ARGUMENT

FIFRA, which regulates pesticides, and the FHSA, which regulates household toxins, preempt any state from adopting additional or different "labeling" requirements. Proposition 65 requires businesses to provide "clear and reasonable warnings." For consumer products, including pesticides, these warnings may be given through a sign or display in the retail store, and are *not* required to appear on the product's labeling. Proposition 65 therefore is not preempted under the specific and exclusive preemption provisions of these two federal statutes.

In upholding the validity of Proposition 65, the court of appeals properly applied this Court's long-standing rules that state statutes are not to be preempted unless this is the "clear and manifest purpose of Congress", *Rice* v. *Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947), and that the presumption against preemption is particularly strong in areas of health and safety regulation. *Hillsborough County* v. *Automated Med. Labs*, 471 U.S. 707, 719 (1985). Moreover, under this Court's recent decision in *Cipollone v. Liggett Group, Inc.*, No. 90-1038, 1992 U.S. LEXIS 4365 (June 24, 1992) (hereinafter "*Cipollone*"), the presumption against preemption "reinforces the appropriateness of a narrow reading" of a preemption provision. *Id.* at *26.

Petitioner argues extensively that Proposition 65 is preempted due to "conflict" with the goals of FIFRA and the FHSA. But as the Court ruled in *Cipollone*, when

Congress has enacted an explicit preemption clause, "there is no need to infer congressional intent to pre-empt state laws from the substantive provisions of the legislation . . . [since] Congress' enactment of a provision defining the preemptive reach of a statute implies that matters beyond that reach are not preempted." *Cipollone* at *24-25. Thus, while Congress could impose on the several states a uniform system of health hazard disclosure requirements for household products and pesticides, it has scrupulously avoided doing so. Instead it chose to adopt narrow preemption provisions, and while Petitioner asserts that the Congressional choice was improper, the district court and the court of appeals properly honored it.

In the only appellate decision related to this case, a New York statute was found not be preempted by the Court of Appeals for the Second Circuit, *New York Pesticide Coalition v. Jorling*, 874 F.2d 115 (2d Cir. 1989) (hereinafter "*Jorling*"), a decision explicitly followed by the Ninth Circuit in *Allenby*. Thus, this case presents no conflict among the circuits.[5/] Accordingly, no review by this Court is needed or appropriate.

ARGUMENT

I. THE CASE INVOLVES A SINGLE STATE LAW AND DOES NOT PRESENT ANY NATIONWIDE ISSUES THAT MERIT THE COURT'S REVIEW

In a strained effort to capture the Court's attention, Petitioner predicts that because of the Ninth Circuit's

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5. Petitioner's claim of a conflict between the Ninth Circuit's ruling and this Court's decision in *Kordel v. United States*, 335 U.S. 345 (1948) (Pet. 21-22) is incorrect. As discussed *infra* at 13, *Kordel* construed the meaning of "labeling" under a different federal statute, and with reference to the federal government's authority to regulate deceptive advertising claims, not in the context of preemption of state laws.

decision, hordes of states will now adopt their own versions of Proposition 65, leading to a multiplicity of warning requirements. This is pure speculation. Almost six years since its adoption in 1986, Proposition 65 remains unique among the fifty states. While similar laws have been considered in a few states, none have been adopted. Whether such statutes will be enacted, what type of requirements they will impose, whether these requirements will even implicate federal interests, how the statutes will be applied, and how the state and lower federal courts will interpret such statutes and reconcile them (if necessary) with FIFRA and the FHSA, are all matters of conjecture.

Moreover, Petitioner's far-fetched assertions about the "disastrous consequences" (Pet. 12) that Proposition 65 will have on federal regulation are contradicted by what the federal agencies themselves say about the statute. William Reilly, the Administrator of EPA (which administers FIFRA), has written: "[t]he law simply warns people about their exposure to carcinogenic or reproductively toxic chemicals at levels exceeding 'no significant risk.' It is hard to argue with providing information to the public."[6/] In that same letter, Reilly pointed out that a 1988 White House Working Group had concluded that the economic costs of Proposition 65 were "relatively minimal," praised the statute's reliance on market incentives to reduce consumers' exposures to toxic chemicals, and noted that industry's predictions of dire consequences from the operation of Proposition 65 (regurgitated by Petitioner here) had proven to be unfounded. *Id.* at 1-2.[7/]

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6. Attachment F to Declaration of Clifford Rechtschaffen at 1, Clerk's Record ("CR") 34.

7. The Reilly letter was written to Health and Human Services ("HHS") Secretary Louis Sullivan because industry had requested HHS to issue an administrative regulation preempting Proposition 65 as applied to products regulated by the Food and Drug Administration.

II. FIFRA DOES NOT PREEMPT PROPOSITION 65

A. FIFRA Only Preempts State "Labeling" Requirements; Proposition 65 Does Not Require "Labeling" Within the Meaning of the Express Preemption Provision of FIFRA

In 1972, Congress first included a provision within FIFRA addressing the authority of states to regulate pesticides. Section 24 of FIFRA now provides:

> § 136v Authority of States
>
> (a) In general
>
> A State may regulate the sale or use of any federally registered pesticide or device in the State, but only if and to the extent the regulation does not permit any sale or use prohibited by this subchapter.
>
> (b) Uniformity
>
> Such State shall not impose or continue in effect any requirements for labeling or packaging in addition to or different from those required under this subchapter.

7 U.S.C. § 136v.

1. Point-of-Sale Signs Satisfy Proposition 65

Proposition 65's "safe harbor" regulations explicitly state that point-of-sale signs comply with the warning

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Reilly argued that "there are very strong reasons not to move forward with federal pre-emption of the law." *Id.* at 1.

requirement. While labels are one authorized method (Cal. Code Regs., tit. 22, § 12601(b)(1)(A)), the regulations also allow a warning through "Identification of the product at the retail outlet in a manner which provides a warning. Identification may be through shelf labeling, signs, menus, or a combination thereof." *Id.* § 12601(b)(1)(B). The warning material is required only to be "displayed at the retail outlet with such conspicuousness . . . as to render it likely to be read and understood by an ordinary individual under customary conditions of purchase or use." *Id.* § 12601(b)(3). It might be located immediately adjacent to the product, or in some other location where it is likely to be seen by purchasers of the product.[8/]

2. Point-of-Sale Signs Are Not "Labeling" as Defined in FIFRA

FIFRA defines "labeling" as follows:

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8. Petitioner argues that Cal. Code Regs., tit. 22, § 12601(b)(5), which states that manufacturers "shall provide a warning to any person to whom the product is sold or transferred," requires the warning signs to flow through the chain of distribution. This section does not require manufacturers to provide the warning signs themselves, just sufficient information to advise the next party of the need to give a warning. As the California Health and Welfare Agency (the state agency with authority to promulgate implementing regulations under Proposition 65) explained in its Statement of Reasons accompanying adoption of this rule, the regulation "merely attempts to ensure that goods passing through a distribution chain are accompanied by warning materials *or information*, so that "the person who finally distributes the product to the consuming public will have knowledge of the need to warn, and will do so." (Final Statement of Reasons at 30-31, Attached to Declaration of Clifford Rechtschaffen, CR 34.) (Emphasis added.) Thus, it does not require that the materials flow with the product, simply that the party handling the product at some point be advised of its nature.

> The term "labeling" means all labels and all written, printed, or graphic matter--
>
> (A) accompanying the pesticide or device at any time; or
>
> (B) to which reference is made on the label or in literature accompanying the pesticide or device(.)

7 U.S.C. § 136(p). Petitioner argues that if the product and the graphic material are in physical proximity to each other at any single point in the entire process from manufacture through use, then the material is labeling. This construction, however, would be contrary to clear case law, EPA's interpretation of the law, and to the purposes of FIFRA.

The court of appeals, consistent with *Cipollone's* instruction that specific preemption clauses are to be narrowly construed, 1992 U.S. LEXIS 4365 at *26, rejected this expansive construction, logically reasoning that:

> FIFRA's definition of labeling cannot encompass every type of written material accompanying the pesticide at any time. If this were true, then price stickers affixed to shelves, sheets indicating that a product is on sale, and even the logo on the exterminator's hat would all constitute impermissible labeling.

In so finding, the court followed the only other reported case on the meaning of "labeling" under FIFRA, *New York Pesticide Coalition v. Jorling, supra*, in which the Second Circuit also rejected a FIFRA preemption challenge to a state pesticide notification requirement. The court in *Jorling* dismissed the claim that such notification materials were "labeling," noting that "'labeling' comprises those materials designed to *accompany the product through the*

stream of commerce to the end user, but not those designed to notify purchasers of services or the general public." *Jorling*, 874 F.2d at 120 (emphasis added). This approach--focusing on whether the materials travel through the stream of commerce with the product--is fully consistent with the purposes of the preemption clause and existing case law.

Moreover, two specific provisions of FIFRA clearly recognize that the term "labeling" does not encompass all types of informational materials that are used in connection with the sale or distribution of FIFRA-registered products.

First, FIFRA specifically mandates that any "labeling" be available to the consumer *during use* of the product, which necessarily means that a point-of-sale sign that is not taken home with the product cannot be "labeling." A FIFRA-registered product is defined as "misbranded" unless information required to appear on the label or labeling is "likely to be read and understood by the ordinary individual under customary conditions of purchase *and use*." (§ 136(q)(1)(E).) (Emphasis added.) Thus, if a pesticide company attempted to satisfy a "labeling" requirement by including the required information in point-of-sale materials, the product would be misbranded and violate the law.

Second, although all FIFRA labeling must be pre-approved by EPA, the statute separately regulates other claims made as part of the distribution and sale of a product, a provision that would be entirely superfluous if all such claims were already part of the approved "labeling." In 1972, Congress amended the statute to prohibit the sale or distribution of a product "if any claims made for it as a part of its distribution or sale substantially differ from any claims made for it . . . in connection with its registration(.)" 7 U.S.C. § 136j(a)(1)(B), Pub. L. No. 92-516 §12(a)(1)(B), *reprinted in* 1972 U.S.C.C.A.N. 1139, 1159. This amendment was

necessary only because Congress recognized that many materials used as part of a product's "sale or distribution" in fact are not labeling.

Nor is the court of appeals' decision inconsistent with this Court's decision in *Kordel v. United States*, 335 U.S. 345 (1948), in which the Court construed the definition of labeling in the Food, Drug and Cosmetic Act (which has no express preemption provision). In *Kordel*, an individual had made deceptive and false statements about foods, but claimed exemption from the law because the statements were made in various brochures and advertisements mailed separately from the actual food products themselves. *Id.* at 346-47. The materials in question contained the only instructions for use of the product, none being on the package itself, thus the court found that they constituted "an essential supplement to the label." *Id.* at 348. Accordingly, this Court found that to exclude such materials from the definition of labeling in that case would "create an obviously wide loophole" that would frustrate the Act's purpose of protecting consumers. *Id.* at 349. As the court of appeals noted, *Kordel* considered the term "labeling" in the context of the need to assure governmental jurisdiction over misleading promotion, not in the context of preemption, with its much narrower purpose of easing nationwide distribution. Pet. App. at 11a-12a. *Kordel*, born of the need to prevent deception, cannot be mechanically applied to a case dealing with Congress' preemptive intent.[9/]

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9. Unlike FIFRA, the Food, Drug and Cosmetic Act has no specific provision prohibiting claims that "substantially differ" from those made during the registration process, 7 U.S.C. § 136j (a)(1)(B), *supra*. Under FIFRA, Congress has acted to assure that neither EPA nor the courts need to expand the definition of "labeling" in order to prevent such circumvention of the Act's requirements.

B. The Preemptive Scope of FIFRA Is Governed by Its Express Preemption Clause

Petitioner argues extensively (Pet. 17-21) that Proposition 65 is impliedly preempted because it will cause consumer confusion and undermine the purposes of FIFRA, thus inviting this Court to undertake the type of broad analysis it rejected in *Cipollone*. In *Cipollone*, (unlike here), one of the explicit purposes of the Cigarette Labeling Act's preemption clause was to guard against "diverse, nonuniform and confusing" regulations, 15 U.S.C. § 1331 (1982 & Supp. 1992). This Court nonetheless found it unnecessary to consider whether state law was impliedly preempted because it undermined the objectives of Congress, given the statute's express preemption language. *Cipollone* at *24-25.

Even prior to *Cipollone*, this Court ruled in *Mortier* that FIFRA does not generally or impliedly preempt state or local laws, but instead preempts only to the extent it specifically so provides. Any inference that Congress intended to occupy an entire field or assert a dominant federal interest cannot be squared with the explicit authority of states under FIRFA to regulate "sale or use" of pesticides. Nor is any intent to preempt anything other than labeling requirements apparent in the legislative history. Quite the opposite, the legislative history states Congressional intent quite clearly: "States are left free to impose whatever restrictions they may wish (other than labeling and packaging)." H.R. Rep. No. 511, 92nd Cong., 1st Sess. (September 25, 1971). Or, as this Court found, "To the contrary, the statute leaves ample room for States and localities to supplement federal efforts even absent the express regulatory authorization of § 136v(a)." *Mortier*, 111 S.Ct. at 2486.

As this Court stated with respect to the *Mortier* plaintiffs' claims of "disaster" from non-federal regulation: "As with the specter of the gypsy moth, Congress is free to find that local regulation does wreak such havoc and

enact legislation with the purpose of preventing it." *Mortier,* 111 S.Ct. at 2487.[10/]

III. PROPOSITION 65 IS NOT PREEMPTED BY THE FHSA

A. The FHSA Only Preempts Nonidentical "Labeling" Requirements; Proposition 65 Neither Requires "Labeling" Nor Imposes Nonidentical Requirements

The FHSA's preemption clause provides that where a hazardous substance is subject to a cautionary labeling requirement under the act, no state may "establish a cautionary labeling requirement . . . designed to protect against the same risk of illness or injury unless such cautionary labeling requirement is identical to the labeling requirement [under the FHSA]." 15 U.S.C. § 1261n (b)(1)(A). The Ninth Circuit correctly ruled that Proposition 65 point-of-sale warnings did not fall within the statute's narrow preemption clause for two independent reasons: first, such warnings are not "labeling," and second, they are not necessarily nonidentical to federal requirements. Pet. App. at 17a.

1. Proposition 65 Does Not Require "Labeling" As Defined by the FHSA

"Labeling" under the FHSA is defined even more narrowly than under FIFRA, because it includes only

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10. Petitioner's claims about the impact that Proposition 65 would have on FIFRA's labeling scheme are in any case unsupported by any competent evidence. The district court reviewed Petitioner's "expert" declarations purporting to show that Proposition 65 undermined the purposes of federal law, and found them to be incompetent and unpersuasive. Pet. App. at 26a.

labels on the immediate container of any hazardous substance, or on any accompanying literature that provide "*directions for use*." 15 U.S.C., § 1261(n).[11/] It does not encompass point-of-sale signs or other means of consumer notification that do not provide "directions for use." Since Proposition 65 explicitly allows businesses to warn through point-of-sale signs or other methods that do not contain "directions for use", it is not "labeling" under the FHSA.

To escape this straightforward conclusion, Petitioner contends that a Proposition 65 warning is the same thing as "directions for use." The court of appeals found this argument not just contrary to Congressional intent, but "nonsensical." Pet. App. at 18a. Congress limited "labeling" to the subset of accompanying literature containing "directions for use"; as the district court found, Petitioner's argument would "read the phrase 'where there are directions for use' right out of the statute." Pet. App. at 23a, n. 2.

Petitioner seeks to draw the Court's attention to a letter from (now former) CPSC General Counsel Clement D. Earhardt, III discussing the term "directions for use," but misleads the Court about the status and import of that letter. The letter was *not* part of the record below, either before the district court or court of appeals. Petitioner filed a motion near the end of the appellate briefing schedule requesting that the Ninth Circuit take judicial notice of the letter, but the court of appeals never

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11. The statute defines "label" as "a display of written, printed or graphic matter upon the immediate container of any substance." 15 U.S.C. § 1261(n). "Labeling" includes all "accompanying literature which provide directions for use, written or otherwise." 15 U.S.C. § 1261(n)(2). The CPSC has defined "accompanying literature" to be "any placard, pamphlet, booklet, sign or other written, printed or graphic matter or visual device that provides directions for use, written or otherwise, and that is used in connection with the display, sale, demonstration, or merchandising of a hazardous substance. . . ." 16 C.F.R. § 1500.3(c)(9) (1992).

granted it.[12]

Moreover, Petitioner's argument that the letter is entitled to deference based on *Chevron U.S.A. Inc. v. Natural Resources Defense Council*, 467 U.S. 837, 844 (1984) is wholly misplaced. The general counsel does not have rulemaking authority or responsibility for administering the FHSA.[13] Moreover, his opinion is not a long-standing interpretation of the CPSC based on its actual administrative practice, and in fact has never been applied by the agency in any regulatory or enforcement context. In addition, although CPSC is not a party to this action, the letter is clearly litigation-inspired, in that it was sent in the midst of the briefing schedule before the Ninth Circuit, and in response to a request by Petitioner. Thus, the counsel's letter is most appropriately analogized to positions taken by agency counsel in the course of litigation, which this Court has said are not entitled to deference. *Bowen* v. *Georgetown Univ. Hospital*, 488 U.S. 204, 212 (1988).

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12. The Ninth Circuit had ample grounds for refusing to supplement the record with this letter so far into the case. *Trans-Sterling, Inc. v. Bible*, 804 F.2d 525, 528 (9th Cir. 1985); *Pyramid Lake Paiute Tribe of Indians v. Hodel*, 882 F.2d 364, 367 (9th Cir. 1989). The court also apparently denied a motion by Respondents to supplement the record with a letter from EPA approving a company's request to add a Proposition 65 warning to its existing FIFRA label. The letter provides further evidence that even if Proposition 65 is construed to require "labeling", there is no conflict between the statute and FIFRA, since a company can potentially comply with Proposition 65 by supplementing its EPA-approved label.

13. CPSC regulations emphasize that legal opinions of the General Counsel "may be changed or superseded by the Commission." 16 C.F.R. §1000.7(a) (1992).

2. Proposition 65 Warnings Are Not "Nonidentical" to Federal Requirements

Regardless of whether Proposition 65 warnings are interpreted as labeling that provides "directions for use", they are not preempted because the FHSA only displaces state requirements that are "nonidentical" to federal standards. Congress wanted to "permit States to adopt requirements identical with the Federal requirements for substances subject to the Federal Act, and to enforce them to complement Federal enforcement." *See* H.R. Rep. No. 2166, 89th Cong., 2d Sess. (1966), *quoted in* 1966 U.S.C.C.A.N. 4097. The Ninth Circuit properly cited this as an alternative ground for rejecting Petitioner's express preemption claims, noting "Proposition 65 warnings are not necessarily nonidentical to the warnings required under the FHSA". Pet. App. at 18a.

As Petitioner acknowledges, the FHSA does not require that any specific language be used on its labels. Pet. at 29. The statute requires that labels contain "the signal word "WARNING" or CAUTION" and words that describe the potential hazard. 15 U.S.C. § 1261(p)(1)(D) & (E). Proposition 65 likewise does not mandate the use of any particular language, but requires only that the warning provide a clear statement of the health risks posed by the chemical in question, Cal. Code Regs., tit. 22, § 12601(a), which directly parallels the FHSA's requirements.

As the court of appeals recognized, the same warning message can be used to comply with both statutes. Pet. App. at 18a. The record below contained evidence of at least one company that had done precisely that, a warning which was reviewed and informally approved by the State.[14/]

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14. *See* Declaration of Dr. Steven Book, ¶¶ 3-5. (CR 46.)

Petitioner protests that a warning message containing a reference to "the State of California", cited as an example by the Ninth Circuit, would undermine the FHSA label. Pet. at 29. Even if this claim were true (and the district court found no evidence to support it), the court of appeals merely offered the message as one alternative that could satisfy both federal and state law; other warning messages, which do not refer to the "State of California", can also be used.[15/]

B. The Preemptive Scope of the FHSA is Limited to Its Express Preemption Clause

Since the FHSA, like FIFRA, contains express preemption language, *Cipollone* precludes the implied preemption arguments urged by Petitioner. In any event, it is clear that Congress intended to enact a "limited preemption amendment [that] relates only to labeling." *See* H.R. Rep. No. 2166, 89th Cong., 2d Sess. (1966), *quoted* in 1966 U.S.C.C.A.N. 4097. Congress further narrowed the preemption clause in 1976. The original version preempted "any and all" state laws for cautionary labeling "of any substance or article" which differed from the "requirements or exemptions of the FHSA."[16/] The 1976 (and current) clause restricts preemption to only those instances where there is a federal labeling requirement in effect and a State imposes a different

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15. The warning language for consumer products suggested in the regulations that includes a reference to "the State of California" is not mandatory. The regulations also endorse another warning message (for alcoholic beverages) which omits this reference entirely, Cal. Code Regs., tit. 22, § 12601(b)(4)(E). Petitioner may dispute that references to the State of California are not required, but exactly what language is sufficient to comply with Proposition 65 has yet to be litigated. This is a matter that properly should be decided in the first instance in the courts of California, and not by this Court.

16. Child Protection Act of 1966, Pub. L. No. 89-756, § 4(b), 80 Stat. 1303 (1966), *reprinted* in 1966 U.S.C.C.A.N. 1524.

labeling requirement that seeks to warn about the same hazards presented by a consumer product.

The fact that Congress preserved many areas of state authority in the FHSA further negates any inference of a broad preemptive intent. Under the statute, states are free to ban entirely products which could otherwise be lawfully sold under the FHSA, so long as the state standards afford a higher degree of consumer protection than the federal requirements. 15 U.S.C. § 1261n (b)(4); *see* S.R. Rep. No. 94-251, 94th Cong., 2d sess. (1976), *reprinted in* 1976 U.S.C.C.A.N. 1004. States also may impose labeling requirements that protect against different consumer risks than those addressed by federal law. 15 U.S.C. § 1261n (b)(1)(A).

Petitioner also contends that Proposition 65 undermines the objectives of federal law because its warning provision will impair the integrity of the FHSA's labeling requirement and undermine the goal of "uniformity in labeling." Pet. at 26-27. But as Congress made explicit in 1976, it did not intend to impose a uniform warning system:

> This preemption scheme is designed to meet the competing interests of those who view Federal requirements as merely minimum standards and those who would opt for uniform national requirements.

S.Rep. No. 251, 94th Cong., *supra*, *reprinted in* 1976 U.S.C.C.A.N. 993, 1004.

As in FIFRA, the congressional concern here was to ease interstate distribution practices for national manufacturers, not to impose a uniform warning system. In any event, Petitioner's contention that Proposition 65 somehow undermines the FHSA's labeling scheme is unsupported by any valid or competent evidence. Pet. App. at 26a.

CONCLUSION

The petition for a writ of certiorari should be denied.

Respectfully submitted,

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In the
Supreme Court of the United States

OCTOBER TERM, 1991

CHEMICAL SPECIALTIES MANUFACTURERS ASSOCIATION, INC.
Petitioner,

vs.

CLIFFORD L. ALLENBY;
JOHN K. VAN DE KAMP, ESQ.,
Respondents.

Petition for a Writ of Certiorari to the United States Court of Appeals for the Ninth Circuit

BRIEF OF AMICUS CURIAE COMMITTEE FOR UNIFORM REGULATION AND LABELING IN SUPPORT OF PETITIONER

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No. 91-1957

IN THE
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Respondents.

INTEREST OF AMICUS CURIAE

Pursuant to Supreme Court Rule 37, the Committee for Uniform Regulation and Labeling respectfully submits this

amicus curiae brief in support of the granting of the Petition for Writ of Certiorari.

Amicus curiae Committee for Uniform Regulation and Labeling ("CURL") is a trade association comprised of approximately forty companies and other entities in the food industry and related industries. Within its membership are many of the largest and best known food producers in the United States, including American Home Products Corporation, Anheuser Busch Companies, Inc., Best Foods Baking Group, Campbell Soup Company, Carnation Company, The Coca-Cola Company, Gerber Products Company, H.J. Heinz Company, Hershey Foods Corporation, Thomas J. Lipton, Inc., PepsiCo, Inc., The Procter & Gamble Company and The Quaker Oats Company.

CURL is dedicated to providing the American consumer with food products that are wholesome, nutritious, safe, properly packaged and accurately labeled pursuant to the uniform standards for food labeling embodied in federal law.

CURL and its members are affected by the Ninth Circuit's decision in the instant case. Federal regulatory statutes governing the manufacture and sale of food products, like the statutes at issue in the case at bench, confer upon the federal government sole authority to determine the content of labels

and labeling. The Ninth Circuit's determination below that state-mandated point-of-sale warnings do not constitute "labeling" will impact the legal obligations of the members of CURL and threatens to undermine the vitally important federal regulatory scheme governing the national food supply.

If the Ninth Circuit's decision is allowed to stand, the various states, relying upon the similarity between the regulatory schemes at bar and those for food products, will doubtless argue that they may properly require point-of-sale warnings concerning food products. (Indeed, the State of California is already making such arguments in a pending case: *CURL v. Allenby,* United States District Court, Northern District, No. C 88 0730 EFL.) It is self-evident that public confidence in food product safety and nutrition would be jeopardized if the various states were permitted to require point-of-sale (e.g., supermarket) warnings that contradict or are inconsistent with federally-approved food labels.

SUMMARY OF ARGUMENT

The federal regulatory schemes for uniform labeling in the industries at bar (pesticides and consumer products containing hazardous substances) expressly preempt state labeling. So also do the federal regulatory schemes for meat

products and poultry products, in remarkably similar language. The federal regulatory scheme for labeling other food products preempts state nutritional labeling. Other federal regulatory schemes impliedly or expressly preempt state labeling with respect to numerous other products. Thus, it is apparent that if the Ninth Circuit's decision restricting the definition of labeling is allowed to stand, it will affect a large segment of the nation's economy and will undermine numerous federal regulatory schemes, including, most importantly, those governing the nation's food supply.

Congress has determined that maintaining the confidence of the American people in the safety and wholesomeness of such products requires that there be uniform federal standards for labeling, which standards insure the communication of relevant information in a coherent and reliable fashion. The intent of Congress would be frustrated by permitting the several states each to require the interjection of additional warnings at the point of sale. For the typical supermarket shopper, the coherent communication of reliable information pursuant to federally-approved labels on meat and poultry products, for example, might then be replaced by a cacophony of federal and state-sanctioned messages that inevitably undermine the coherence and reliability of the federally-approved labels.

In *Kordel v. United States*, 335 U.S. 345 (1948) ("*Kordel*"), this Court construed the term "labeling" to embrace unattached written material intended to communicate information to consumers about the use of the product. So also did the Second Circuit in *New York Pesticide Coalition v. Jorling*, 874 F.2d 115 (2d Cir. 1989) ("*Jorling*"). The Ninth Circuit's determination that point-of-sale warnings do not constitute labeling depends upon the proposition that such warnings are directed to mere purchasers as distinct from consumers. That proposition is plainly wrong. A shopper buying food in the supermarket is in fact a consumer and exposing the shopper to a point-of-sale warning constitutes labeling. Accordingly, *Kordel* and *Jorling* require reversal of the Ninth Circuit's decision.

ARGUMENT

A. The Ninth Circuit's Decision Impacts Not Only The Federal Regulatory Schemes At Issue Here, But Also Other Federal Regulatory Schemes That Preempt State Labeling, Including Those Governing Meat Products, Poultry Products, Food Nutrition And Other Important Products.

In the decision at bar, the Ninth Circuit held that state-mandated point-of-sale warnings are not preempted by the Federal Insecticide, Fungicide and Rodenticide Act, 7 U.S.C. §§ 136-136y (1988 and Supp. II 1990) ("FIFRA") or by the Federal Hazardous Substances Act, 15 U.S.C. §§ 1261-1277 (1988 and Supp. II 1990) ("FHSA").

FIFRA vests the United States Environmental Protection Agency with sole authority to regulate the labeling of pesticides. 7 U.S.C. § 136v(b). Labeling is broadly defined to include all "written, printed or graphic matter . . . accompanying the pesticide . . . at any time." 7 U.S.C. § 136(p)(2) (1988).

FHSA likewise vests the Consumer Product Safety Commission with authority exclusively to regulate cautionary labeling with respect to risks associated with hazardous

substances in consumer products other than the pesticides regulated pursuant to FIFRA. 15 U.S.C. § 1261 note (b)(1)(A). Like FIFRA, the FHSA defines labeling broadly, embracing "all accompanying literature where there are directions for use, written or otherwise." 15 U.S.C. § 1261(n)(2). The Commission's regulations provide that the term "accompanying literature" includes point-of-sale placards, signs or displays. 16 C.F.R. § 1500.3(c)(9) (1992).

These are not the only federal regulatory schemes that vest federal agencies with sole authority to regulate labeling and define labeling broadly. Indeed, as we demonstrate below, there are several other such schemes.

Of primary importance to CURL, and of immense importance to the American public, are the federal regulatory schemes governing the food industry. The United States Department of Agriculture comprehensively regulates meat and poultry products pursuant to the Federal Meat Inspection Act, 21 U.S.C. §§ 601-695 ("FMIA"), and the Poultry Products Inspection Act, 21 U.S.C. §§ 451-470 ("PPIA"). The Department of Agriculture conducts continuous inspections of meat and poultry slaughtering and processing operations, and regulates, reviews and requires premarket approval of the contents of all meat and poultry product labels, labeling and packaging. 21 U.S.C. §§ 457(c) and 607(d). Both of these acts

expressly prohibit the states from imposing other labeling requirements,[1] 21 U.S.C. §§ 467(e) and 678, and both define labeling broadly to include:

> all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article.

21 U.S.C. §§ 453(s) and 601(p). See *Jones v. Rath Packing Co.*, 430 U.S. 519, 530-532 (1977) (Federal Meat Inspection Act preempts state labeling law).

Pursuant to the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301-394, the United States Food and Drug Administration comprehensively regulates food safety. 21

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[1] The express preemptive language in the meat and poultry acts is very similar to that in FIFRA, 7 U.S.C. § 136v(b) (1988), and FHSA, 15 U.S.C. § 1261 note (b)(1)(A). Section 678 of the FMIA provides in pertinent part: "marking, labeling, packaging, or ingredient requirements in addition to, or different than, those made under this chapter may not be imposed by any state . . . ." 21 U.S.C. § 678. The PPIA contains identical language. 21 U.S.C. § 467(e).

U.S.C. §§ 341-350a.[2] This act employs the same broad definition of "labeling" quoted in the preceding paragraph, 21 U.S.C. § 321(m), and expressly preempts the states from imposing other nutritional labeling requirements. 21 U.S.C. § 343-1.

Federal authority over labeling extends to a number of other products besides food products and those governed by FIFRA and FHSA. The Food, Drug, and Cosmetic Act vests the Food and Drug Administration with authority over the labeling of drugs, 21 U.S.C. § 352, employs the same broad definition of labeling, 21 U.S.C. § 321(m), and preempts the states as to drug safety and efficacy labeling. See *Pharmaceutical Society of State of New York v. Lefkowitz*, 586 F.2d 953, 958 (2d Cir. 1978). The Federal Seed Act, 21 U.S.C. §§ 1551-1611, confers comparable authority with respect to seed labeling upon the Department of Agriculture and, again, defines labeling broadly. 7 U.S.C. §§ 1561(18), 1562, 1591-1601.

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[2] The Food, Drug, and Cosmetic Act prohibits commerce in food products that are adulterated, 21 U.S.C. § 331(a), and provides that a food product is adulterated if it contains a substance that renders the food injurious to health. *Id.* § 342(a)(1). The act prohibits the addition of any substance that may render a food injurious to health, 21 U.S.C. § 342(a)(2)(A), or that contains unsafe substances or levels of substance including food additives, color additives, animal drug residues, and pesticide residues. 21 U.S.C. §§ 321(s), 321(t), 342(a)(2)(B), (C) and (D), 342(c), 348, 360(b) and 376. Foods containing a chemical found to induce cancer are adulterated and prohibited under federal law. 21 U.S.C. § 348(c)(3).

Federal criminal statutes make it a felony to tamper with the labeling of any consumer product and incorporate by reference the broad definition of labeling set forth in the Food, Drug, and Cosmetic Act. 18 U.S.C. § 1365(a), (b) and (g)(2).

By its decision construing the scope of the term "labeling," the Ninth Circuit will affect the interpretation of all of these statutes. Accordingly, the decision of the Ninth Circuit is significant not only to those who are regulated by FIFRA and FHSA, but to other important sectors of the American economy as well.

B. The Ninth Circuit's Decision Jeopardizes Regulatory Schemes For Food Products By Undermining Public Confidence In The Integrity Of Federally-Approved Food Labels.

As indicated above, federal regulatory authority over the food industry is broad indeed. In conferring such broad federal authority, Congress intended to assure American consumers as to the safety, wholesomeness and integrity of the American food supply. See *Carolene Products Co. v. United States*, 323 U.S. 18, 21-25 (1944); *Federal Security Administrator v. Quaker Oats Company*, 318 U.S. 219, 230-231 (1943).

Federal control over labeling plays a central role in the regulatory process. As the Second Circuit has observed in the context of FIFRA, Congress prohibited state labeling for the purpose of "preserving the force of the information contained" in the federally-approved labels. *Jorling, supra,* 874 F.2d at 119. State-mandated communications cannot be permitted to "impair the integrity" of those labels. *Ibid.*

The decision in the case at bar, however, may be construed to support state-mandated warnings contained in labeling. This result could have its greatest impact on CURL members and other food producers through the application of California's Proposition 65, the so-called Safe Drinking Water and Toxic Enforcement Act of 1986 California Health and Safety Code §§ 25249.5-25249.13.

Proposition 65 impairs the integrity of food labels. It establishes a competing regulatory scheme whereby the state independently establishes a list of chemicals "known to the state to cause cancer or reproductive toxicity," *id.* § 25249.6, and prohibits businesses from exposing individuals to detectable levels of any such listed chemicals without first providing state-mandated warnings. *Id.* §§ 25249.6, 25249.8, 25249.10(c), 25249.11(c). The scheme presumes that *any* detectable amount is significant. It effectively forces each business to choose either to warn (about inconsequential but detectable levels) or to bear

the burden of establishing that a given level is *not* a significant risk. Point-of-sale warnings are an approved method of performing the duty to warn. *Id.* § 25249.11(f); Cal. Code Regs. tit. 22, § 12601(b).[3]

The state-mandated warning must be in the following form: "WARNING: This product contains a chemical known to the State of California to cause . . ." either "cancer" or "birth defects or other reproductive harm," as the case may be. Cal. Code Regs. tit. 22, § 12601(b)(4)(A) and (B).

The labeling of meat and poultry products, as we have demonstrated above, is subject to exclusive federal regulation and constitutes a representation by the federal government that the labelled contents are wholesome and safe. The interjection of point-of-sale warnings, declaring ominously that a given food product contains a chemical "known to the State of California" to cause cancer or reproductive harm, obviously draws into question the reliability of the federally-approved label. The conflict could scarcely be plainer: the federal government has

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[3] Whether there is any real alternative to point-of-sale warnings is extremely doubtful. Label warnings are also approved by Proposition 65, *ibid.*, but, as indicated above, are preempted by federal law. Other warning methods fail to meet Proposition 65's requirement of "clear and reasonable" warning prior to exposure. See *Ingredient Communication Council, Inc. v. Van de Kamp*, 2 Cal.App.4th 1480, 4 Cal.Rptr.2d 216 (1992) (rejecting warning system on basis of failure to include in-store product-specific warnings).

determined the food product at issue to be safe, but the state thinks otherwise.[4]

Moreover, if the Ninth Circuit's decision that Proposition 65 point-of-sale warnings do not constitute labeling is allowed to stand, the states would be encouraged to mandate other point-of-sale warnings that further undermine the integrity of federally-approved food labels.[5]

For the typical supermarket customer, the result of permitting state-mandated point-of-sale warnings would be to replace the coherent communication of reliable information pursuant to federally-approved labels with a cacophony of federal and state-sanctioned messages that inevitably undermine the coherence and reliability of the federal labels.

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[4] The point-of-sale warnings required by Proposition 65, in addition to conflicting with federal labels, are arguably misleading. The required warning -- that the product in question is "known to the State of California" to cause cancer or reproductive harm -- conveys the impression that the product has in fact caused such harm to consumers, when in fact, proof of actual harm to consumers is not necessary to trigger the warning requirement. See Cal. Health and Safety Code § 25249.10(c) and Cal. Code Regs. tit. 22, §§ 12701 et seq. (determinations of no significant cancer risk) and §§ 12801 et seq. (determinations of no observable reproductive toxicity effect).

[5] Proposition 65-type legislative proposals are pending in Illinois (HB 3795) and Massachusetts (HB 612), and a Proposition 65-type initiative has qualified for the November 1992 statewide ballot in Ohio. If any of these measures become law, a regulatory crazy-quilt will result.

As applied to food products, state-mandated point-of-sale warnings thus frustrate the intent of Congress to preserve "the force of the information contained in the [federal] label," *Jorling, supra,* 874 F.2d at 119.

C. The Ninth Circuit's Determination That Point-Of-Sale Warnings Are Not Directed To Consumers Is Plainly Wrong As Applied To The Sale Of Food, And Places The Ninth Circuit In Conflict With Decisions Of This Court And The Second Circuit.

In *Kordel, supra,* this Court held that supplemental literature provided by a drug manufacturer constituted labeling because it advised the consumer on how to use the drug. 335

U.S. at 348.[6] In an effort to distinguish the case at bar from *Kordel*, the Ninth Circuit asserted that the point-of-sale warnings mandated by Proposition 65 are not aimed at the "ultimate user" but at the "purchaser." Pet. App. at 12a.

This assertion makes no sense whatever, particularly as applied to food products (which are quite clearly included within Proposition 65's broad reach). Supermarket shoppers are obviously consumers as well as purchasers of food. And it is equally obvious that the point-of-sale warnings envisioned by Proposition 65 are intended to impart information to those consumers about the proper use of the food they purchase: namely, that foods "known to the State of California" to cause

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[6] In the companion case of *United States v. Urbuteit*, 335 U.S. 355 (1948), this Court considered the fact that leaflets were shipped separately from the products they described to be "immaterial where the advertising matter that was sent was designed to serve and did in fact serve the purposes of labeling." *Id.* at 357.

Kordel and *Urbuteit* were, respectively, a criminal action against an individual and a civil action seeking seizure of electronic machines claiming to aid in the diagnosis and cure of cancer, diabetes, tuberculosis, arthritis and paralysis. These cases demonstrate that the Ninth Circuit's restrictive definition of labeling not only enlarges the power of states to interfere with federal regulatory schemes, but also enlarges the opportunities of others to evade those schemes. Conversely, this restrictive definition limits the exercise of regulatory authority by numerous federal agencies. It is imperative that a proper and expansive definition of "labeling" be maintained to effectuate the full extent of federal regulation mandated by Congress.

cancer or reproductive harm should be consumed with caution or not at all.

This Court in *Kordel* and the Second Circuit in *Jorling* both counselled that a practical examination must be conducted into the relationship between the federal label and the other communication at issue; if the latter is aimed at the consumer and will impair the integrity of the federal label, it constitutes preempted labeling. Proposition 65's point-of-sale warnings fail on both counts. Apparently recognizing that it has no power to require cancer or reproductive toxicity warnings to be included on federally-approved product labels, the State of California seeks to circumvent federal preemption by use of point-of-sale warnings. The Ninth Circuit's narrow and unrealistic view that such point-of-sale warnings do not constitute labeling is at odds with both *Kordel* and *Jorling* and should be reversed.

CONCLUSION

For the foregoing reasons, the Petition for Writ of Certiorari should be granted.

DATED: July 6, 1992.

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IN THE

Supreme Court of the United States

OCTOBER TERM, 1991

CHEMICAL SPECIALTIES MANUFACTURERS ASSOCIATION, INC.,

Petitioner,

v.

CLIFFORD L. ALLENBY; JOHN K. VAN DE KAMP, ESQ.

Respondents.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE NINTH CIRCUIT

BRIEF OF *AMICUS CURIAE* CHEMICAL MANUFACTURERS ASSOCIATION IN SUPPORT OF THE PETITION FOR A WRIT OF CERTIORARI

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No. 91-1957

IN THE
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Chemical Specialties Manufacturers Association, Inc.

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Respondents.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE NINTH CIRCUIT

BRIEF OF *AMICUS CURIAE* CHEMICAL MANUFACTURERS ASSOCIATION IN SUPPORT OF THE PETITION FOR WRIT OF CERTIORARI

INTEREST OF *AMICUS CURIAE*

The Chemical Manufacturers Association (CMA) is a non-profit trade association whose member companies represent 90 percent of the productive capacity for basic industrial chemicals in the United States. CMA member companies are located throughout the United States, and are subject to many federal and State environmental regulations, including those governing the labeling of pesticides and hazardous substances that are involved in this case. The federal and State regulatory structures impact the ability of chemical companies to market their products across the country. The Association is filing this *amicus* brief because of its strong interest in clarifying the effect of federal law on State regulations.

Pursuant to Rule 37.2 of the Rules of this Court, CMA requested and received the written consent of all parties to file this *amicus* brief. The consents of Petitioner and Respondents accompany this brief.

If the Court of Appeals' decision stands, substantial new regulatory authority will effectively be vested in State governments despite the dictates of federal law. The balance created by Congress in shared federal-State authority will be upset under the Ninth Circuit decision.

In addition, the decision exacerbates the impact of multiple State regulations, despite the existence of comprehensive, uniform programs adopted by Congress. The doctrine of federal pre-emption and the very principles of Federalism promote uniformity in those areas, as in this case, that have significant health and safety implications. The Ninth Circuit decision will undermine the purposes and objectives of the federal labeling requirements for pesticides and consumer chemicals.

SUMMARY OF REASONS FOR GRANTING THE PETITION

The Court should grant the petition for certiorari because the Ninth Circuit decision upsets the federal-State balance of authority adopted by Congress in federal programs related to environmental, health and safety protection. If the decision stands, Congressional limits on the exercise of State regulatory authority will be undermined, threatening the existence of uniform, comprehensive federal regulatory programs. The Ninth Circuit decision also undercuts this Court's recent decision in *Gade v. National Solid Wastes Management Ass'n*, ____ U.S. ___, 60 U.S.L.W. 4587 (June 18, 1992), and therefore merits the Court's review.

Regardless of the pre-emption category under which this case is analyzed, the clear text of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) and the Federal Hazardous Substances Act (FHSA) pre-empt any state enactment

relating to labeling for pesticides and consumer chemical products. FIFRA and FHSA reflect a Congressional mandate for shared federal-State authority over pesticides and consumer chemicals. The notable exception to that shared power is labeling, where federal law controls exclusively. The effect of the Ninth Circuit decision is to endorse conflicting regulatory results, transferring control over labeling to State governments, contrary to Congressional intent.

The Ninth Circuit decision should also be reviewed by this Court because it conflicts with decisions in other federal Circuit Courts of Appeal. Certiorari should be granted to provide States, the regulated community, and the lower courts guidance on the pre-emption standard applied under FIFRA and FHSA.

ARGUMENT

I. CERTIORARI SHOULD BE GRANTED BECAUSE THE NINTH CIRCUIT DECISION HAS A BROAD IMPACT ON FEDERAL ENVIRONMENTAL, HEALTH AND SAFETY LAWS

This case involves an issue that has increasingly occupied the federal courts: pre-emption of State law by federal law. Since January 1, 1989, more than 395 cases raising pre-emption issues have been brought before the Supreme Court and the Courts of Appeal. Although these cases did not all involve the pre-emptive effect of the same statute, the number of cases is testimony to the uncertainties which reign in federal pre-emption analysis. *See Cipollone v. Liggett Group, Inc.*, ____ U.S. ____, 60 U.S.L.W. 4703 (June 24, 1992) (Scalia, J., concurring in part and dissenting in part). The Ninth Circuit decision will compound those uncertainties by giving pre-emptive effect only to the most precise, detailed statements of Congressional intent.

A. Background

In 1986, the State of California enacted the Safe Drinking Water and Toxic Substances Act (Proposition 65).[1] The Act requires the State to list substances considered to be carcinogens or reproductive toxins. *Id.* Manufacturers of products containing these substances -- regardless of concentration or actual toxic effect -- are required to provide warnings about the content of the products. *See Pet. for Cert. at 3-5.* Exceptions from the warning requirements are available if the manufacturer can show no risk, under extremely conservative risk and exposure assumptions. Proposition 65 forces manufacturers to provide point-of-sale labeling. *Id.* at 5.

The petitioner, the Chemical Specialties Manufacturers Association (CSMA), brought suit for declaratory judgment, arguing that shelf labeling required under Proposition 65 is pre-empted by the specific language of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), 7 U.S.C. § 136 *et seq.* and the Federal Hazardous Substances Act (FHSA), 15 U.S.C. § 1261 *et seq.*. FIFRA and FHSA impose a comprehensive federal precautionary labeling system for pesticides and consumer chemicals, respectively.

The main objectives of the FIFRA and FHSA regulatory schemes are the protection of human health, safety, and the environment. In the area of labeling, the federal government has sole regulatory discretion. As first enacted in 1947, FIFRA was primarily a licensing and labeling statute.

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[1] Because Proposition 65 imposes an undue burden on interstate commerce, CMA filed an action for declaratory judgment seeking federal Occupational Safety and Health Act (OSHA) pre-emption of the workplace warning requirement. *Chemical Manufacturers Ass'n et al. v. Cal. Health and Welfare Agency, et al.*, No. CIVS -88 -1615 LKK-JFM (E.D. Cal.). The case is currently stayed by order of the District Court pending federal OSHA's review of California's state plan amendment purporting to adopt the Proposition 65 workplace requirements.

Ruckelshaus v. Monsanto Co., 467 U.S. 986, 991 (1984). Due to public concern about the safety of pesticides and their effect on the environment, Congress amended FIFRA several times, transforming it from a simple labeling law into a comprehensive regulatory statute. *Id.* Today, FIFRA is a carefully crafted system of regulatory procedures, substantive rights, and obligations that balances the needs of interstate commerce with the public concern for safety. Having amended the Act five times (1972, 1975, 1978, 1980, 1988) in the last 20 years, Congress has given the structure of the Act careful consideration and reflection.

FIFRA permits State governments to assert jurisdiction over the sale or use of a regulated product. FIFRA § 24(a); 7 U.S.C. § 136v(a). A State's regulatory authority is limited only by an express prohibition on State labeling or packaging requirements "in addition to or different from" the FIFRA requirements. *Id.*, § 24(b); 7 U.S.C. § 136v(b). Labeling, in turn, is defined by FIFRA as "all labels *and all other written, printed or graphic matter*" that accompanies the product at any time or to which some reference is made. *Id.*, § 2(p)(2); 7 U.S.C. § 136(p)(2) (emphasis added).

The U.S. Environmental Protection Agency (EPA) is charged with implementing FIFRA. EPA conducts detailed scientific assessments to determine whether product risk and exposures warrant specific warning language. *See Pet. for Cert. at 10-11.*

Like FIFRA, the FHSA is a comprehensive regulatory statute which vests exclusive authority over labeling of consumer chemicals (except pesticides) with the federal government. Congress' commitment to federal control over labeling was demonstrated six years after enactment of FIFRA. The Act was amended to pre-empt State labeling requirements not identical with federal law but covering the same risks. 15 U.S.C. § 1261 note (b)(1)(A); Pub. L. No. 89-756 § 4(b)(1)(A); 80 Stat. 1305 (1966).

FHSA governs the sale, use, packaging and labeling of consumer chemicals. As in FIFRA, labeling under the FHSA includes material affixed to products or which accompany the product. FHSA § 2(n); 15 U.S.C. § 1261(n). State authority is limited to packaging or use requirements, subject to approval from the federal government. *Id.* § 1261 note (b)(1)(B); Pub. L. 89-756 § 4(b)(1)(B).

The FHSA complements the authority of the Consumer Product Safety Commission (CPSC) to regulate chronic hazards -- like carcinogens -- under the Consumer Product Safety Act (CPSA), 15 U.S.C. § 2051 *et seq.* Notably, the CPSA also restricts State labeling regulations not identical with CPSC requirements. *Id.*, § 2075. The CPSC is required to conduct comprehensive assessments of the data on chemicals before issuing warning requirements.

B. The Ninth Circuit Decision Undermines Federal Environmental, Health and Safety Law

The Ninth Circuit found that FIFRA and FHSA did not pre-empt Proposition 65 because the required warnings were not "labeling" as that term is used in the federal statutes. *Chemical Specialties Manufacturers Ass'n v. Allenby*, 958 F. 2d 941 (9th Cir. 1992). This unnecessarily narrow reading of the statutes threatens the fundamental balance of regulatory authority Congress has adopted throughout the major environmental, health and safety laws.

The United States has the most comprehensive system of environmental law in the world. In enacting these laws, Congress sought to reconcile the legitimate police powers of the States with the federal government's interest in environmental protection, public health and safety, and interstate commerce. In virtually every environmental statute there is some provision for State divergence from the Congressionally-established standard, subject however to federal control in the areas most critical to the federal objective. *See, e.g.*, Clean Water Act § 510, 33 U.S.C. 1370 (State effluent limita-

tions); Solid Waste Disposal Act § 9004, 42 U.S.C. § 6991c (State administration of underground storage tank program); Toxic Substances Control Act § 18, 15 U.S.C. § 2617 (conditions for State regulation of toxic substances). The approach is consistent with the Constitutional requirement to give effect to the State's police powers, while maintaining a uniform standard in the areas of national concern (*i.e.*, interstate commerce).

The Ninth Circuit, however, would read Congress' attempts to preclude State regulation with a jaundiced eye. In taking a needlessly narrow view of statutory pre-emption provisions, rather than the statute as a whole, *United States v. Morton*, 467 U.S. 822, 828 (1984), the Ninth Circuit decision has the effect of requiring Congress to speak with a detail that strains the bounds of credulity, if not practicality.

For example, the Clean Water Act prohibits States from adopting or enforcing any effluent limitation that is less stringent than those in effect under the federal program. Clean Water Act § 510, 33 U.S.C. § 1370 (1972). *See also International Paper Co. v. Ouellette*, 479 U.S. 481, 490 (1987) (Clean Water Act pre-emption of state common law). The Act further defines effluent limitations as State or federal "restrictions" on amounts discharged to water. *Id.*, § 502(11), 33 U.S.C. § 1362(11). On the face of this provision, the federal standards establish a regulatory minimum. Suppose next that a State determines that the federal standard has had a significant economic impact, and that a lesser effluent limitation would preserve industry and jobs. The State could -- in the guise of economic development -- adopt a lower "discharge rate" for its industry, arguing that the lower rate does not amount to a restriction. This result comports with the narrow approach taken by the Ninth Circuit, yet completely and utterly defeats the clear purpose intended by Congress.

C. The Ninth Circuit Decision Negates This Court's Recent Pre-emption Decision in Gade.

Less than one month ago, the Court held that the federal Occupational Safety and Health Act (OSHA), 29 U.S.C. § 651-678 (1970), pre-empts State enactments which have an impact on federal workplace standards. *Gade v. National Solid Wastes Management Ass'n*, ____ U.S. ___, 60 U.S.L.W. 4587 (June 18, 1992). The State law at issue in *Gade* was arguably consistent with the federal standards, although broader in scope than the federal requirements. The similarities between OSHA and the statutes involved in the present petition suggest that the result in *Gade* will be undermined unless the Court grants certiorari.

Like FIFRA and FHSA, OSHA was intended to impose a degree of federal control in an area subject to multiple, potentially conflicting regulations. OSHA contains, like FIFRA and FHSA, a system of shared federal-State authority over workplace health and safety. As in FIFRA and FHSA, OSHA carefully limits the role of the States in regulating occupational safety and health. State workplace standards on subjects for which a federal standard is in effect are expressly pre-empted, similar to pre-emption under FIFRA and FHSA. A State may assert regulatory authority under OSHA only by adopting a state plan approved by the federal agency, with more stringent State regulations requiring OSHA's express approval, akin to the procedure required under the FHSA. OSHA § 18; 29 U.S.C. § 667.

Under *Gade*, even State standards which supplement the federal statutory objectives and purposes are pre-empted. The Ninth Circuit's narrow construction, read in conjunction with the Court's recent decision in *Cipollone*, ___ U.S.___, 60 U.S.L.W. 4703 (June 24, 1992), could lead to exactly the inconsistent result identified by Justice Scalia:

> If taken seriously, it would mean, for example, that if a federal consumer protection law provides that no state agency or court shall assert jurisdiction under state law over a workplace safety issue with respect to which a federal standard is in effect, then a state agency operating under a law dealing with a subject other than workplace safety (e.g., consumer protection) could impose requirements entirely contrary to federal law -- forbidding, for example, the use of certain safety equipment that federal law requires . . . . [T]he result is extraordinary: The statute that says *anything* about pre-emption must say *everything*; and it must do with great exactitude, as any ambiguity concerning its scope will be read in favor of preserving state power. *Id.* at ___, 60 U.S.L.W. at 4715 (Scalia, J., *concurring* in part and *dissenting* in part) (emphasis in original).

II. CERTIORARI SHOULD BE GRANTED TO PREVENT EROSION OF THE REGULATORY BALANCE ADOPTED BY CONGRESS

A. Proposition 65's Shelf Labeling Requirement is Pre-empted by the Plain Language of FIFRA and FHSA.

Regardless of whether a particular claim of pre-emption is categorized as express or implied, the "ultimate task in any pre-emption case is to determine whether State regulation is consistent with the structure and purpose of the statute as a whole." *Gade v. National Solid Wastes Management Ass'n*, _____ U.S. at ____, 60 U.S.L.W. at 4590. If the language and structure of a federal enactment clearly limit a State's ability to regulate, pre-emption must be found. *Jones v. Rath Packing Co.*, 430 U.S. 519, 525 (1977); *Shaw v. Delta Air Lines, Inc.*, 463 U.S. 85, 95 (1983); *Fidelity Federal Savings & Loan Ass'n v. De la Cuesta*, 458 U.S. 141, 152-153 (1982).

Thus, the Court need go no further than a simple analysis of FIFRA and FHSA to find pre-emption. Shelf labeling regarding product content is clearly "other written, printed or graphic matter." The warnings accompany the product as they are present at the point-of-sale. *See Kordel v. United*

States, 335 U.S. 345 (1948) (supplemental literature constitutes labeling under the federal Food Drug & Cosmetic Act). The Proposition 65 warnings therefore constitute labeling for the purposes of FIFRA and FHSA, and are pre-empted.

The content of Proposition 65 shelf labeling is not dispositive. Because shelf labeling is in addition to and not identical to the federal labels -- a possibility recognized and prohibited by Congress -- the state regulation is pre-empted. The Ninth Circuit decision has the result of holding that material not physically affixed to the container does not constitute labeling -- a result clearly inconsistent with the terms of FIFRA and FHSA and this Court's prior reasoning. The petition for certiorari should be granted to prevent the manifestly inaccurate reading given FIFRA and FHSA by the Ninth Circuit.

B. Even if Proposition 65's Shelf Warnings are Not Labeling, They Have an Adverse Effect on FIFRA and FHSA, and are Pre-empted by Federal Law.

Even assuming that Proposition 65 shelf warnings are not considered labeling pursuant to FIFRA and FHSA, the warning requirement is nevertheless impliedly pre-empted by federal law.

Implied pre-emption has been established by this Court in any number of formulations. The policies and purposes served by the federal law, and implicated by the State enactment, have been dispositive. *Schneidewind v. ANR Pipeline Co.*, 485 U.S. 293, 299-300 (1988). The impact of State law on Congress' chosen regulatory method has been considered. *English v. General Electric Co.*, 496 U.S. 72, 110 S. Ct. 2270, 2275 (1990). The degree to which States can diverge from the federal regime has been considered. *International Paper Co. v. Ouellette*, 479 U.S. at 476. The various formulations are all applied in determining whether the State law "stands as an obstacle" to the federal regime, or regulates in a field occupied by the federal law, the two basic standards in

implied pre-emption analysis. *See Cipollone*, ___U.S. at ___, 60 U.S.L.W. at 4706-4707.

The common thread in these apparently different approaches to implied pre-emption analysis is the effect of the state law on the integrity of the federal program or those regulated.[2] *Id.* at ___, 60 U.S.L.W. at 4709-10. As the Eleventh Circuit aptly stated, "it is possible to infer pre-emptive intent solely from effects." *Papas v. UpJohn Co.*, 926 F.2d 1019 (11th Cir. 1991), *vacated and remanded sub nom. Papas v. Zoecon Corp.*, 60 U.S.L.W. 3870-3871, 3878 (June 29, 1992) (quoting *Taylor v. General Motors Corp.*, 875 F.2d 816, 826 (11th Cir. 1989), *cert. denied*, 110 S. Ct. 1781 (1990)) (emphasis added). In and of itself an "effects" test is not dispositive of a pre-emption claim, but assists in developing the type of information needed to balance the presumption in favor of state law that applies in pre-emption cases. *Cipollone*, ___U.S. at ___, 60 U.S.L.W. at 4706 *(quoting Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947).

In *Morales v. Trans World Airlines, Inc.*, 60 U.S.L.W. 4444 (June 1, 1992), this Court construed the preemptive effect of the Airline Deregulation Act on state guidelines related to airline advertising. In finding that the ADA preempted the state guidelines, the Court looked to the impact of the state rules on the regulated community and the intended reach of the federal law. *Id.* at 4446-47. The poten-

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[2]As the Court has stated, the label applied to pre-emption analysis in a given case may have substantive implications. *Gade* at ___U.S. at ___, 60 U.S.L.W. at 4590. This case, like *Gade*, does not turn on whether pre-emption is express or implied, but indeed on the very effects Congress sought to avoid in adopting a comprehensive labeling regime for consumer chemicals.

tial economic effect of the state guidelines was also important in this analysis.[3]

In the present case, Propostion 65 has a direct, significant impact on the integrity of the FIFRA and FHSA regulatory regimes, as well as substantial impact on chemical manufacturers.

Under Proposition 65, the State of California summarily lists products considered to be carcinogens and reproductive toxins by other organizations, such as the International Association for Research on Cancer (IARC). *Cal. Code Regs.* tit. 22, § 12601. Similarly, proposed regulations will establish an expedited method for setting Proposition 65 regulatory levels. *See Cal-EPA Considering New Method for Setting No Significant Risk Levels*, Chem. Reg. Rep. (BNA) 798 (Sept. 20, 1991). No independent scientific assessment is conducted in the listing process. The summary listing procedures do an injustice to the scientific assessments made pursuant to FIFRA and FHSA.

Crystalline silica is a good example of the absurd results under Proposition 65 which impact the federal labeling programs. IARC has recently listed crystalline silica as a "probable" carcinogen. Crystalline silica is one of the most ubiquitous substances on earth, and constitutes a large percentage of the earth's crust. The common form of the chemical is sand, such as that used in children's sandboxes or in construction applications. The evidence that crystalline silica is a human carcinogen is limited at best. *See, e.g.*, McDonald, *Silica, Silicosis and Lung Cancer* (Editorial), 46 Brit. J. Indus. Medicine 289-91 (1989).

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[3]Notably, the *Morales* decision adopts a broader construction of the preemption provision than would be suggested under the Ninth Circuit's decision below. *See Cipollone*, ___ U.S. at ___, 60 U.S.L.W. at 4715 (Scalia, J., concurring in part and dissenting in part).

The Consumer Product Safety Commission (CPSC), which administers the FHSA, has not issued any requirement that sand for children's use be labeled for its health effects (although it would clearly be within CPSC's purview to do so). At least at this juncture, the CPSC has not determined that sand warrants a warning label about its theoretical health effects.

Proposition 65 will require inflexible warnings of the theoretical carcinogenic effect of sand. In the absence of a FHSA warning, the Proposition 65 warning supplants the CPSC's expertise and judgment. The FHSA labeling program, designed to foster confidence and safety in consumer products nationwide, is undermined, and the public subjected to warnings of negligible risks. Over-labeling creates the risk of triggering information overload, de-emphasizes true risks, and is ultimately harmful to health and safety.

Not only does Proposition 65 undermine the role of science and the role of the federal agency in regulatory decisions, the California law has a clear impact on interstate commerce. Congress' choices in FIFRA and FHSA reflect an implicit balancing between health and safety needs and interstate commerce. As well noted in the petition for certiorari, the Ninth Circuit decision has a clear effect on interstate commerce. *Pet. for Cert.* at 16-17, 26-27. Other states may be persuaded to adopt similar or inconsistent regulations following a broad grant of authority like that contained in the Ninth Circuit holding. The resulting distortions of the federal labeling system, and health and safety protection, are exactly the effect Congress sought to prevent with uniform labeling requirements under FIFRA and FHSA.

Contrary to the Ninth Circuit's decision, the State law need not be inconsistent with the federal law in order to infer pre-emption. *Morales*, ___ *U.S. at* ___, 60 U.S.L.W. at 4447; *Mackey v. Lanier Collection Agency and Service, Inc.*, 486

U.S. 825, 829 (1988) (pre-emption of state retirement law that was arguably consistent with federal law). It is enough that the state law impact the federal program in some way.

Even where the state and federal programs share a common goal, pre-emption may be found. In *Gade*, compliance with both the federal and state law was possible. ____U.S. at ___, 60 U.S.L.W. at 4591. The fact that the State regulation had another purpose arguably within the State's police powers (hazard communication to the public) was not dispositive. *Id.* The effect of the State regulation on the administration of the federal occupational safety and health program, and on the regulated industry, controlled.

The decision of the Ninth Circuit that the regulated community can comply with both Proposition 65, and FIFRA and FHSA, is plainly at odds with the decisions in *Morales*, *Gade* and *Mackey*. *See Chemical Specialties Manufacturers Ass'n . v. Allenby*, 958 F.2d at 948-949. Although the Ninth Circuit was correct to look at compliance as a factor in determining the effect of Proposition 65's labeling requirement, that factor alone does not decide the pre-emptive effect of federal law on state law. Proposition 65 clearly has an impact on the federal regulatory structure for consumer chemicals, and implicates interstate commerce. The petition for certiorari should therefore be granted.

III. THE NINTH CIRCUIT DECISION CONFLICTS WITH DECISIONS IN OTHER FEDERAL COURTS OF APPEAL

The Ninth Circuit's decision employed no careful analysis of the structure or purpose of FIFRA, or of the effect of the State enactment on Congress' chosen regulatory scheme. The Ninth Circuit decision simply and superficially transforms all FIFRA and FHSA pre-emption questions into a narrow review of what constitutes labeling. The Court should grant certiorari to provide guidance to States, the regulated community, and the lower courts on the FIFRA and FHSA preemption standards.

New York State Pesticide Coalition v. Jorling, 874 F.2d 115 (2d Cir. 1989) provides an example of an analysis starkly at odds with the Ninth Circuit decision. *Jorling* involved a state requirement that pesticide applicators provide public notice of their activities. According to the Second Circuit, the notices provided by professional pesticide applicators were not labeling, but rather a notification program. *Id.* at 119. By contrast, Proposition 65 shelf labeling falls more readily into the labeling area in which State activity is prohibited; shelf labeling has a closer relationship to products than the conditions for chemical use. *Id.*

The Second Circuit held that FIFRA did not pre-empt the state use regulation. The *Jorling* Court had a clear understanding that labeling necessarily must be considered in the relevant circumstances. *Id.* at 119. The *Jorling* Court did nothing to disturb the understanding that the federal government had exclusive authority over labeling, or that state regulation may have have a negative effect on the FIFRA regulatory regime. *Id.* at 118-119. *See also New York Pesticide Coalition v. Jorling*, 704 F. Supp. 26, 29-30 (1989).

This Court has clearly indicated that local and state regulation of labeling would fall within the area pre-empted by FIFRA. *Wisconsin Public Intervenor v. Mortier*, 111 S. Ct. 2476 (1991). The Court distinguished local use permit regulations from labeling: "local use regulations -- unlike labeling or certification -- do not fall within an area that FIFRA's 'program' pre-empts or even plainly addresses". *Id.* at 2487. Proposition 65 shelf warnings are clearly not use restrictions of the type approved in *Jorling* or *Mortier*, but are in fact labeling.

The Eleventh Circuit has also expressed a view on FIFRA pre-emption, holding that FIFRA impliedly pre-empts state common law tort claims for inadequate labeling. *Papas v. Upjohn Co.*, 926 F.2d at 1021. This view is shared by the Fourth and Tenth Circuits. *Worm v. American Cyanamid Co.*,

___ F. 2d ___, 1992 U.S. App. LEXIS 14154 (4th Cir. 1992); *Arkansas Platte & Gulf Partnership v. Van Waters & Rogers Inc.*, 959 F.2d 158 (10th Cir. 1992).

Common law tort judgments have as much of a regulatory effect as any other form of state enactment. *Cipollone*, ___*U.S. at* ___, *60 U.S.L.W. at 4708 (plurality opinion). See International Paper Co. v. Ouellette*, 479 U.S. 481 (1987); *Wisconsin Dep't of Industry v. Gould, Inc.*, 475 U.S. 282 (1986). The Eleventh Circuit decision found that to the extent a tort judgment can be seen to impose a labeling requirement, FIFRA pre-empted the action. *Papas*, 926 F.2d at 1021.

Although this Court has recently remanded the *Papas* case to the Eleventh Circuit for further consideration in light of *Cipollone*, 60 U.S.L.W. 3878 (June 29, 1992), the prior decision recognized the strong federal role in FIFRA: "The statute's language, by itself, is a powerful limit on state power over labeling." *Papas*, 926 F. 2d at 1023. In sharp contrast, the Ninth Circuit decision has the effect of approving all state regulation regardless of its impact on the federal labeling programs. Because of the potential for confusion arising from the various circuit court views, the petition for certiorari should be granted.

CONCLUSION

For the reasons stated above, the Petition for a Writ of Certiorari filed by the Chemical Specialties Manufacturers Association should be granted.

Respectfully submitted,

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July 6, 1992

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Re: Chemical Specialties Manufacturers Association v. Allenby, No. 91-1957

Dear Mr. Walls:

On behalf of the Chemical Specialties Manufacturers Association, we hereby consent to the filing of an amicus curiae brief by the Chemical Manufacturers Association in support of the Petition for a Writ of Certiorari.

Sincerely,

Lawrence S. Ebner
Attorney for Chemical Specialties Manufacturers Association

cc: Stephen S. Kellner, Esq.

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RE: Chemical Specialties Manufacturers Ass'n v. Allenby;
Petition for Certiorari (Supreme Court No. 91-1957)

Dear Mr. Walls:

Respondents consent to the Chemical Manufacturers Association filing an amicus brief in support of the Petition for Certiorari in this matter.

Sincerely,

DANIEL E. LUNGREN
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cc: Charles O'Connor, III (Attorney for Petitioner)

Supreme Court, U.S.
FILED
SEP 11 1992
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No. 91-1957

IN THE
Supreme Court of the United States
OCTOBER TERM, 1992

CHEMICAL SPECIALTIES MANUFACTURERS ASSOCIATION,
Petitioner,
v.
STEVEN A. BOOK, *et al.*,
Respondents.

On Petition for Writ of Certiorari to the United States Court of Appeals for the Ninth Circuit

PETITIONER'S REPLY BRIEF

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PETITIONER'S REPLY BRIEF

ARGUMENT

In their Opposition Brief, Respondents (hereinafter "the State") deny that California Proposition 65 represents a nationally significant threat to the viability of the federal cautionary labeling programs for consumer products under the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA") and the Federal Hazardous Substances Act ("FHSA"). The State argues that Proposition 65 is merely one state's law; disputes that the Ninth Circuit's holding that Proposition 65 warning requirements do not constitute requirements for "labeling" under FIFRA or FSHA directly conflicts with Supreme Court and Second Circuit precedents on the meaning of "labeling"; and contends that no implied preemption analysis of Proposition 65 is permissible in light of *Cipollone v. Liggett Group, Inc.*, 112 S. Ct. 2608 (1992), since FIFRA and FHSA contain express preemption provisions. For reasons given below, the State protests CSMA's petition too much with too little basis.

I. THE NATIONAL SIGNIFICANCE OF THE FEDERAL PREEMPTION ISSUE IN THIS CASE IS NOT DIMINISHED BECAUSE ONLY CALIFORNIA HAS ENACTED PROPOSITION 65.

The State tries to downplay the nationwide impact of its Proposition 65 warning requirements on the federal labeling of consumer pesticide and hazardous substance products by quoting EPA Administrator Reilly on the value of "providing information to the public," and by noting that as yet no other state has adopted such a law. Br. for Resp'ts in Opp. to Pet. for Writ of Cert. ("Resp't") at 8. The State's use of Mr. Reilly's letter on Proposition 65 is both misleading and troubling since the State knows full well that the letter "does not express the Agency's official position" on preemption under FIFRA. Letter from EPA Counsel James H. Curtin to

Edward G. Weil (Aug. 7, 1990), Ex. B to Weil Decl. (R. 41). Indeed, EPA counsel expressly instructed the State not to use Mr. Reilly's letter to support the inference which the State asks the Court to draw here.

Although no other states have passed Proposition 65-type legislation yet, California's enactment of this landmark law itself creates a nationally significant issue. With a resident population exceeding 29 million (representing almost 12 percent of the total U.S. population) California is by far the most populous state, and the dominant state market for consumer products. As such, California law unavoidably shapes marketing and labeling practices nationwide for consumer products like household pesticides and hazardous substances.[1]

Equally important, the State's opposition to CSMA's petition ignores altogether the deleterious impacts of Proposition 65 on the integrity of the federal labeling program caused by its point-of-sale warnings for cancer and reproductive effects, which conflict with the precautionary label warnings mandated by FIFRA and FHSA; on product liability exposure of national consumer pesticide and hazardous substances marketers, who disseminate such conflicting point-of-sale and product label warnings; and on consumers in California and elsewhere, who must choose which conflicting warnings to believe. *See* Pet. for Writ of Cert. ("Pet.") at 17-21. Through FIFRA's and FHSA's statutory preemption provisions, Congress sought to protect the integrity of the federal cautionary labeling program—the centerpiece of regulation under those Acts. The State urges the Court to overlook the formidable obstacle to achievement of this congressional goal simply because to date California is the only offending state. The Court should resist, however, and not condone even a

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[1] As indicated in the affidavit of Thayre Talcott, an industry labeling expert, once a large state like California requires precautionary warnings for a consumer product, manufacturers as a matter of commercial practicality will seek to modify their labels. Talcott Decl. ¶ 14 (R. 21).

single state's (much less California's) obstruction of the integrity of the federal labeling program.[2]

II. THE COURT OF APPEALS ERRED BY FAILING TO RECOGNIZE THAT PROPOSITION 65 WARNING REQUIREMENTS CONSTITUTE "LABELING" AND ARE AN OBSTACLE TO THE FIFRA LABELING PROGRAM.

Despite FIFRA's broad definition of labeling, 7 U.S.C. § 136(p)(2) (1988) ("written, printed, or graphic matter . . . accompanying the pesticide . . . at any time"), the State argues that Proposition 65 warning requirements escape FIFRA's reach by not requiring manufacturers to produce the actual retail sign; by permitting retail warnings "through shelf labeling, signs menus or a combination thereof"; and by terminating the warning obligation at the retail outlet. As the case precedents of this Court and the Second Circuit teach, however, these arguments are immaterial and do not change the character of Proposition 65 warning requirements as labeling under FIFRA.

A. Written Warning Information Provided by the Manufacturer, Accompanying the Product, and Intended for the Pesticide Purchaser Is Labeling Under FIFRA.

Proposition 65 regulations expressly require that a manufacturer of consumer pesticides (and each successive transferee) *"shall provide a warning* to any person to whom the product is sold or transferred unless the product is packaged or labeled with a clear and reasonable warning." Cal. Code Regs. tit. 22, § 12601(b)(5) (1992) (emphasis added). Furthermore, the very purpose of this requirement is *"to ensure that goods passing through a distribution chain are accompanied by warning materials*

---

[2] The detrimental impact of Proposition 65 goes beyond FIFRA and FHSA and encompasses other federal health, safety and environmental laws. *See amicus curiae* briefs of the Chemical Manufacturers Association and the Committee for Uniform Regulation and Labeling submitted in support of Petitioner CSMA's certiorari petition.

or information" and "that the person who finally distributes the product to the consuming public will have knowledge of the need to warn, and will do so." Final Statement of Reasons (accompanying Cal. Code Regs. tit. 22, § 12601) at 30-31 (Oct. 6, 1988) (emphasis added). Regardless of whether the manufacturer must provide the actual point-of-sale warning sign, Proposition 65 mandates that the manufacturer distribute with its product the "warning materials or information," so that the required warning accompanies the product to the retailer, who thereby knows to generate a conspicuous display to the purchaser.

The warning information required of the manufacturer under Proposition 65 is labeling within the meaning of FIFRA because it is "designed to be read and followed by the end user" (i.e., the purchaser), *New York State Pesticide Coalition, Inc. v. Jorling*, 874 F.2d 115, 119 (2d Cir. 1989), and because "the primary intent of the federal labeling requirements is to regulate what producers say about their products." *American Meat Inst. v. Ball*, 424 F. Supp. 758, 762 (W.D. Mich. 1976). As EPA explains, " 'labeling' comprises those materials designed to accompany the product through the stream of commerce to the end user." *Jorling*, 874 F.2d at 120.

Whatever form the manufacturer's warning information may take, it satisfies FIFRA's broad definition of labeling. Indeed, as documented by former EPA Assistant Administrator for Pesticides and Toxic Substances Steven D. Jellinek, EPA has long considered to be labeling all such "[b]ulletins, leaflets, circulars, brochures, data sheets, flyers, or other written or graphic printed matter which is referred to on the label or which is to accompany the product." Jellinek Decl. ¶ 75 & Ex. G at 81 (R. 21); *see also* 49 Fed. Reg. 37,960, 37,972 (Sept. 26, 1984) (proposed definition).

Without citation the State asserts that a Proposition 65 point-of-sale warning does not accompany the product because "[i]t might be located immediately adjacent to the

product, or in some other location where it is likely to be seen by purchasers of the product." Resp't at 10. As the Court explained in *Kordel v. United States*, 335 U.S. 345, 350 (1948), however, the State's point is immaterial; "accompany" does not mean physical attachment—"It is the textual relationship that is significant." Furthermore, under Proposition 65 the point-of-sale sign must be "product-specific," that is, it must specifically identify the particular product to which it applies. *Ingredient Communication Council, Inc. v. Lungren*, 4 Cal. Rptr. 2d 216, 225 (Cal. Ct. App. 1992). By requiring this "textual" relationship between the warning and the product, Proposition 65 mandates that the warning be one that "accompan[ies] the pesticide" as that term is used in FIFRA. *See Kordel.*

B. Labeling Need Not Be Present During Product Use.

Finding no support in FIFRA's definition of labeling, the State invokes two particular misbranding and unlawful acts provisions of FIFRA to argue that point-of-sale warnings are not labeling because they need not "be available to the consumer *during use* of the product," and because FIFRA also regulates non-labeling claims. Resp't at 12.

FIFRA's definition of labeling, however, does not contain an exception for material which violates the misbranding prohibitions against labeling that fails to appear "in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use." 7 U.S.C. § 136(q)(1)(E) (1988). Misbranded labeling is still labeling. Further, FIFRA defines labeling to include materials accompanying the pesticide "at any time"—not just at the point of application; under Proposition 65 the warning information accompanies the product not merely "at any time," but all the way from the manufacturer through the channels of trade to the purchaser. Moreover, since the purchaser of consumer pesticides usually is also the end user, the Proposition 65 warning, like FIFRA labeling, "is

designed to be read and followed by the end user." *Jorling*, 874 F.2d at 119.

Finally, EPA's misbranding enforcement authority over pesticide claims which differ substantially from those approved at registration does not support the State's argument. Rather, it addresses unlawful claims made other than by written, printed or graphic means, such as salesmen's oral puffery or misleading broadcast advertising, as well as claims made by non-registrants such as distributors and retailers.

C. FIFRA's Express Preemption Clause Does Not Preclude Implied Preemption Analysis.

Citing the Court's recent decision in *Cipollone v. Liggett Group, Inc.*, 112 S. Ct. 2608 (1992), the State argues that CSMA's certiorari petition is governed solely by express preemption, and that no consideration can be given to implied (field or conflict) preemption. Moreover, the State proposes to obliterate all implied preemption analysis on the erroneous ground that the Federal Cigarette Labeling and Advertising Act's preemption clause has a broader sweep than does FIFRA § 24(b), 7 U.S.C. § 136v(b) (1988). This is not only incorrect given the comparable language in both preemption provisions, but also conveniently allows the State simply to conceal the deleterious effects that Proposition 65 warning requirements have on the integrity of the FIFRA labeling program. *See* Pet. at 17-21.

To the extent express preemption analysis does not confirm FIFRA's preemption of Proposition 65 warning requirements for consumer pesticides, *Cipollone* interposes no bar to traditional implied preemption analysis, especially "conflict" preemption which is governed "by direct operation" of the Supremacy Clause regardless of the presence or scope of a statutory preemption provision. *Brown v. Hotel & Restaurant Employees & Bartenders Int'l Union*, 468 U.S. 491, 501 (1984); *see also Gade v. National Solid Wastes Management Ass'n*, 112 S. Ct. 2374, 2388 (1992); *Jones v. Rath Packing Co.*, 430 U.S.

519 (1977) (holding that a state law regulating labeling of millers' flour is impliedly preempted due to direct conflict with federal law, even though the state law is not expressly preempted). Moreover, in *Wisconsin Public Intervenor v. Mortier*, 111 S. Ct. 2476, 2487 (1991), the Court confirmed that pesticide labeling "fall[s] within an area that FIFRA's 'program' pre-empts." Indeed, when appearing as *amicus curiae* in *Mortier*, the State itself acknowledged that "section 24(b), in precluding state regulation of labeling, evinces a congressional design to occupy the field of labeling regulation."[3] Thus, *Mortier* certainly invites field preemption analysis of FIFRA's prohibition against state labeling requirements.

III. THE COURT OF APPEALS ALSO ERRED BY FAILING TO RECOGNIZE THAT PROPOSITION 65 WARNINGS CONSTITUTE LABELING WITHIN THE MEANING OF FHSA AND ARE AN OBSTACLE TO THE FHSA LABELING PROGRAM.

A. Proposition 65 Warnings Are Implied "Directions for Use."

The State contends that the Proposition 65 warning requirement is not labeling under FHSA on grounds that the point-of-sale display is not "accompanying literature" under FHSA § 2(n), 15 U.S.C. § 1261(n) (1988), because it contains no "directions for use, written or otherwise." To the contrary, by raising the red flags of cancer and birth defects, Proposition 65 impliedly directs purchasers to minimize or avoid exposure. While the Proposition 65 warning admittedly is not a complete or sufficient direction for safe use, its very inadequacy as a use direction creates the sort of problem which Congress sought to prevent by defining FHSA labeling to include "accompanying literature" and then preempting non-identical state labeling requirements.[4]

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[3] *Amicus Curiae* Br. of States of California, Arizona, Indiana, Maryland, New Jersey and Washington Supporting Resp'ts at 9 n.4.

[4] As CPSC interprets § 2(p)(1) in its guidance about cautionary labeling against cancer hazards, 52 Fed. Reg. 34,698, 34,701 (Sept.

By defining "label" under FHSA § 2(n) to include "accompanying literature," Congress intended that point-of-sale information about the safe use of a product be *complete*, and *contain all* of the precautionary labeling required under FHSA § 2(p)(1). Proposition 65 point-of-sale signs omit this required precautionary information, fail to fully instruct purchasers through all the required label statements, and render the hazardous substances product misbranded under FHSA § 2(p)(1), 15 U.S.C. § 1261(p)(1) (1988).

Citing the Ninth Circuit's decision, the State asserts that the foregoing interpretation is "nonsensical," even though it is supported in an Advisory Opinion of the CPSC General Counsel. Authorized to provide "written advisory opinions interpreting the acts the Commission administers," 16 C.F.R. § 1000.7(a) (1992), the CPSC General Counsel determined that a Proposition 65 warning is an implied direction for use: "it conveys the information that, in using the product, steps should be taken to minimize or eliminate exposure," and thus constitutes labeling under FHSA § 2(n). Advisory Op. No. 312 at 3 (Mar. 6, 1991). Conversely, under the Ninth Circuit's interpretation, manufacturers and states alike are free to give partial, erroneous and misleading point-of-sale information about FHSA product safety since (not being a direction for use) that safety information would not constitute accompanying literature subject to misbranding.

B. Proposition 65 and FHSA Warnings Are Not Identical.

The State contends that because FHSA does not specify the precise label warnings, manufacturers can develop language that will satisfy Proposition 65 without violating

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14, 1987), a point-of-sale sign cannot simply warn about a principal hazard; it also must explain the factors which control the degree of risk and the precautions to be taken. Therefore, viewed (as it must) in the context of FHSA as a whole, "directions for use" include cautionary statements about product hazards, like the Proposition 65 warnings.

FHSA. This argument turns FHSA preemption on its head. By authorizing the states "to adopt requirements identical with the Federal requirements" for hazardous substances, Congress permitted the states to enforce FHSA through their own *identical* state laws—not to develop unique state requirements for when and how to warn about the same hazards regulated under FHSA.

Where FHSA's mandatory labeling requirements allow some discretion on wording and the states do not, the two are "non-identical"—even though they may be consistent. The State's interpretation of "identical" would open the door to fifty different state warnings for each hazard regulated under FHSA—all potentially at odds with one another but all arguably consistent with FHSA. Pet. at 24-27. Furthermore, Proposition 65 and FHSA warnings for consumer products are neither consistent nor identical. For FHSA-regulated products, Proposition 65 invariably requires use of the phrase "known to the State" [5] and the signal word "warning," whereas FSHA employs different cautionary language and signal words, depending on the particular product.

C. *Cipollone* Does Not Preclude Implied Preemption Analysis of FHSA.

The State's suggestion notwithstanding, *Cipollone* does not preclude implied preemption analysis simply because FHSA, like FIFRA, contains express preemption language. *See* discussion at 6-7, *supra*. Indeed, the direct conflict between Proposition 65 and FHSA cautionary labeling requirements is an essential part of this case

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[5] The State cannot disown the express regulatory requirement of Cal. Code Regs. tit. 22, § 12601(a) (1992) that the "message must clearly communicate that the chemical in question is *known to the state* to cause cancer, or birth defects or other reproductive harm." (Emphasis added); *see also id.* § 12601(b)(4)(A), (B) (the warning message for consumer products "must include" the language "known to the State of California to cause cancer").

which the court of appeals failed to appreciate, and which the State asks the Court to ignore. *See* Pet. at 24-26.

Further, the FHSA preemption provision ("no State or political subdivision of a State may establish or continue in effect a cautionary labeling requirement," 15 U.S.C. § 1261 note (b)(1)(A)) "sweeps broadly"—not narrowly, as the State implies. *See Cipollone*. The State also misconstrues the legislative history of the 1976 FHSA amendment about balancing minimum standards against uniform national requirements, which demonsrates the broad sweep of FHSA preemption. As amended in 1976, FHSA requires State governments to apply to CPSC for an exemption before imposing any non-identical precautionary labeling requirement, and requires the Commission to consider the "probability of other States . . . applying for an exemption . . . for a similar requirement, and *the need for a national, uniform requirement under [FHSA] for such substance*" before granting an exemption. 15 U.S.C. § 1261 note (b)(3)(A) (emphasis added); *see also* 16 C.F.R. §§ 1061.1-12 (1992). The State has upset this congressionally wrought balance by ignoring the FHSA exemption procedure while imposing different cautionary labeling on hazardous substances.

CONCLUSION

For the foregoing reasons, and those presented in CSMA's Petition, the Court should grant a writ of certiorari.

Respectfully submitted,

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